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42 CFR Parts 417 and 422

Medicare Program; Establishment of the Medicare Advantage Program; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 417 and 422

CMS–4069–F

RIN 0938–AN06

Medicare Program; Establishment of the Medicare Advantage Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule implements provisions of the Social Security Act (the Act) establishing and regulating the Medicare Advantage (MA) program. The MA program was enacted in Title II of The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) on December 8, 2003. The MA program replaces the Medicare+Choice (M+C) program established under Part C of title XVIII of the Act, while retaining most key features of the M+C program.

The MA program attempts to broadly reform and expand the availability of private health plan options to Medicare beneficiaries.

This final rule responds to public comments on a proposed rule published on August 3, 2004 (FR 69 46866).

EFFECTIVE DATE: These regulations are effective March 22, 2005 except for the following changes which will become effective on January 1, 2006: amendment of § 417.600(b); removal of § 417.602 through § 417.638; and amendments to § 417.832(d); and § 417.840.

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Acronyms

Because of the many terms to which we refer by acronym in this final rule, we are listing the acronyms used and their corresponding terms in alphabetical order below:

ABN	Advance beneficiary notice
ACR	Adjusted Community Rate
ACRP	Adjusted Community Rate Proposal
ADL	Activities of Daily Living
AHRQ	Agency for Healthcare Research and Quality
AI/AN	American Indian and Alaska Native
ALJ	Administrative law judge
APA	Administrative Procedure Act
BBA	Balanced Budget Act of 1997
BBRA	Medicare, Medicaid and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999, (Pub. L. 106–113)
BIPA	Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (Pub L. 105–33)
CAH	Critical Access Hospitals
CCPs	Coordinated Care Plans
CMPs	Competitive Medical Plans
CORF	Comprehensive outpatient rehabilitation facility
DSH	Disproportionate Share Hospital
EGPH	Employer and Union Group Health Plans
EOC	Evidence of coverage
ESRD	End-Sage Renal Disease
FEHB	Federal Employees Health Benefits
FFS	Fee-for-Service plans
FI	Fiscal Intermediaries
HCPP	Health care prepayment plan
HHA	Home health agency
HMO	Health Maintenance Organizations
HOS	Health Outcomes Survey
ICF/MR	Intermediate Care Facilities for Mentally Retarded
IHS	Indian Health Service
IPA	Independent Physician Association
ISAR	Intra-Service Area Rate
I/T/U	Indian Health Service, Tribal and Urban Health Program
LEP	Limited English Proficiency
LMRP	Local Medical Review Policy
M+C	Medicare+Choice
MA	Medicare Advantage
MA-PD	Medicare Advantage Prescription Drug
MAC	Medicare Appeals Council
MCOs	Managed Care Organizations
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
MSA	Medical Savings Account
MYBE	Mid-year Benefit Enhancement
OACT	Office of the Actuary
OPM	Office of Personnel Management
PACE	Program All-Inclusive Care for the Elderly
P4P	Pay for Performance
PCP	Primary Care Physician
PDP	Prescription Drug Plan
PFFS	Private Fee-For-Service
POS	Point of Service
PPOs	Preferred Provider Organizations
PSOs	Provider Sponsored Organizations
QI	Quality Improvement
QIO	Quality Improvement Organization
RFB	Religious Fraternal Benefit
SAE	Service Area Expansion
SEP	Special Election Period
SHIP	State Health Insurance Programs

SNF	Skilled Nursing Facility
SNPs	Special Needs Plans

I. Background

A. Medicare Prescription Drug, Improvement, and Modernization Act of 2003

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) was enacted on December 8, 2003. Title II of the MMA makes important changes to the current Medicare+Choice (M+C) program by replacing it with a new Medicare Advantage (MA) program under Part C of Medicare. On August 3, 2004, we published a proposed rule in the **Federal Register** (69 FR 46866) that set forth the provisions that would implement Title II of the MMA. Beginning in 2006, the MA program is designed to:

• Provide for regional plans that may make private plan options available to many more beneficiaries, especially those in rural areas.

• Expand the number and type of plans provided for, so that beneficiaries can choose from Health Maintenance Organizations (HMOs), Preferred Provider Organization (PPO) plans (the most popular type of employer-sponsored plan), Fee-for-Service (FFS) plans, and Medical Savings Account (MSA) plans, if available where the beneficiary lives.

• Enrich the range of benefit choices available to enrollees including improved prescription drug benefits, other benefits not covered by original Medicare, and the opportunity to share in savings where MA plans can deliver benefits at lower costs.

• Provide incentives to plans, and add specialized plans to coordinate and manage care in ways that comprehensively serve those with complex and disabling diseases and conditions.

• Use open season competition among MA plans to

improve service, improve benefits, invest in preventive care, and hold costs down in ways that attract enrollees.

• Enhance and stabilize payments to organizations, improve program design, introduce new flexibility for plans, and reduce impediments to plan participation.

• Advance the goal of improving quality and increasing

efficiency in the overall health care system. Medicare is the largest payer of health care in the world. Medicare can drive changes in the entire health care system.

With these new and improved choices, Medicare beneficiaries, like Federal employees and retirees in the Federal Employees Health Benefits (FEHB) Program, will have the opportunity to obtain improved benefits, improved services, and reduced costs. However, beneficiaries will still be able to remain in traditional Medicare (referred to throughout as ''original'' Medicare), enhanced by the new Part D drug benefit. All will have the opportunity to switch among plans, or to or from original Medicare, during the annual election period (or ''open season'') in November and December.

Over time, participating plans will be under continued competitive pressure to improve their benefits, reduce their premiums and cost sharing, and improve their networks and services, in order to gain or retain enrollees. In addition, we expect plans to use integrated health plan approaches such as disease prevention, disease management, and other care coordination techniques. In doing so, integrated plans that combine the original Parts A and B of Medicare and the new Part D drug benefit and apply these innovative techniques must pass on savings that may result from these care coordination techniques to the enrollee through reduced premiums or additional benefits.

Beginning in 2006, payments for local and regional MA plans will be based on competitive bids rather than administered pricing. MA organizations will submit an annual aggregate bid amount for each MA plan. An aggregate plan bid is based upon the MA organization's determination of expected costs in the plan's service area for the national average beneficiary for providing non-drug benefits (that is, original Medicare (Part A and Part B) benefits), Part D basic prescription drugs, and supplemental benefits if any (including reductions in cost sharing). Our payment to an MA organization for an MA plan's coverage of original Medicare benefits depends on the relationship of the plan's basic A/B bid to the plan benchmark. For a plan with a basic A/B bid below its benchmark, we will pay the MA organization the basic A/B bid amount, adjusted by the individual enrollee's risk factor, plus the rebate amount. (The rebate is 75 percent of the difference between the plan bid and benchmark, and is used to provide mandatory supplemental benefits or reductions in Part B or Part D premiums. The government retains the other 25 percent.) For a plan with a bid equal to or above its benchmark, we will pay the MA organization the plan benchmark, adjusted by the individual enrollee's risk factor. In addition, we would pay the bid amount, if any, for Part D basic coverage. The MMA also requires other adjustments to payments. See the subpart G preamble for a discussion of the geographic Intra-Service Area Rate (ISAR) adjustment and the government premium adjustment (referred to in the MMA as the ''adjustment relating to risk adjustment'').

We will be able to negotiate bid amounts with plans in a manner similar to negotiations conducted by the Office of Personnel Management(OPM) with FEHB plans. We will work with plans to ensure benefit packages meet the needs of our population and that information is made available to beneficiaries so that they can make decisions about which plans best meet their needs.

Finally, in conjunction with the new drug benefit required under Title I of MMA, which is addressed in separate rulemaking found in part 423, changes made in the MMA to the M+C program (now called the MA program) are intended to bring about broad-based improvements to the Medicare program's benefit structure, including improved prescription drug coverage under the MA program. Organizations offering local and regional coordinated care MA plans must offer at least one plan with the Medicare prescription drug benefit or an actuarially equivalent drug benefit.

In addition to the changes because of the MMA, we identified many areas in the proposed rule where we believed we could prevent or reduce unnecessary burden, duplication, or complexity either in interpreting the new MMA provisions or in modifying existing rules to accommodate MA reforms.

B. Relevant Legislation

1. Balanced Budget Act of 1997

Section 4001 of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) added sections 1851 through 1859 to the Social Security Act (the Act) establishing a new Part C of the Medicare program, known as the Medicare+Choice (M+C) program. Under section 1851(a)(1) of the Act, every individual entitled to Medicare Part A and enrolled under Medicare Part B, except for individuals with end-stage renal disease (ESRD), could elect to receive benefits either through the original Medicare program or an M+C plan, if one was offered where he or she lived.

The primary goal of the M+C program was to provide Medicare beneficiaries with a wider range of health plan choices through which to obtain their Medicare benefits. The BBA authorized

us to contract with private organizations offering a variety of private health plan options for beneficiaries, including both traditional managed care plans (such as those offered by HMOs that had been offered under section 1876 of the Act), and new options that were not previously authorized. Four types of M+C plans were authorized under the new Part C, as follows:

- M+C coordinated care plans, including HMOs (with or without point-of-service options (POS)), provider sponsored organizations (PSOs), and PPOs.
- M+C MSA plans (combinations of a high deductible M+C health insurance plan and a contribution to an M+C MSA).
- M+C private fee-for-service (PFFS) plans.
- M+C religious and fraternal benefit (RFBs)plans.

The BBA changed the payment methodology to Medicare health plans and initially afforded beneficiaries more choice of plans nationally. However, payment rates grew modestly in relation to the costs health plans incurred, resulting in fewer health plans participating in the M+C program, decreased choice of plans available to beneficiaries, and fewer extra benefits available to enrollees. Although there were large payment increases in rural areas as a result of the BBA provisions, access to Medicare coordinated care plans declined significantly in rural areas after 1997.

To implement these changes, we published an interim final rule in the **Federal Register** on June 26, 1998 (63 FR 34968); a final rule on February 17, 1999 (64 FR 7968); and a final rule with comment on June 29, 2000 (65 FR 40170).

2. Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 and the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000

The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, Pub. L. 106–113 (BBRA) amended the M+C provisions of the BBA. Many of these amendments were reflected in the June 29, 2000 final rule with comment period. In addition, the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Pub. L. 106–554 (BIPA), enacted December 21, 2000, further amended the M+C provisions of the BBA and BBRA. A final rule containing BIPA provisions was published in the **Federal Register** on March 22, 2002 (67 FR 13278), as well as on August 22, 2003 (68 FR 50855).

These laws enacted subsequent to the BBA made incremental changes to M+C payments and provided financial incentives to plans to participate in the M+C program. While these efforts helped stabilize the M+C program, they did not generally improve plan participation in the M+C program nor did they increase overall beneficiary enrollment or access to plans in rural areas.

3. Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)

The specific sections of Part C of the Social Security Act that were impacted by the MMA are as follows:

Section 1851—Eligibility, election and enrollment.

Section 1852—Benefits and beneficiary protections.

Section 1853—Payments to MA organizations.

Section 1854—Premiums.

Section 1855—Organizational and financial requirements for MA organizations.

Section 1856—Establishment of standards.

Section 1857—Application procedures and contracts with MA organizations.

Section 1858—Special rules for MA regional plans [added by the MMA].

Section 1859—Definitions; Miscellaneous provisions.

This final rule addresses the new MA provisions in Title II of MMA. The requirement in 1858(a)(2)(D) of the Act to conduct a market survey and analysis before establishing MA regions took place concurrent with the publication of the MA proposed rules. The announcement of the establishment of the MA and Prescription Drug Plan (PDP) regions occurred on December 6, 2004. The regions may be found at *http://cms.hhs.gov/medicarereform/mmaregions*.

Provisions of the MMA addressed in this final rule outside of Title II of the MMA include Section 722—Medicare Advantage Quality Improvement Program, of Title VII. Quality improvement provisions in this final rule may be found under Subpart D—Quality Assurance.

C. Codification of Regulations

The final provisions set forth here are codified in 42 CFR Part 422, The Medicare Advantage Program.

The regulations for managed care organizations (MCOs) that contract with CMS under cost contracts will continue to be located in 42 CFR part 417, Health Maintenance Organizations, Competitive Medical Plans, and Health Care Prepayment Plans.

D. Organizational Overview of Part 422

The MMA amended the existing provisions of the Medicare statute found in Part C of Title XVIII, sections 1851 through 1859 of the Act, and added a new section 1858 to the Act. This final rule covers a wide range of topics included in the existing part 422, including eligibility and enrollment, benefits and beneficiary protections, payment, contracting requirements, and grievances and appeals. We have generally retained the organization of the sections from part 422, except for reordering subparts F and G to place the bidding and payment provisions in sequential order.

Where the MMA did not amend existing statute, this final rule does not set forth unchanged regulations text from the previous part 422. Thus, this final rule contains only the necessary revisions to existing part 422. In some subparts of part 422, the only changes are in nomenclature, that is, the replacement of M+C references with MA references. The regulations in that subpart H are not set forth in this final rule. The subparts with substantive changes are as follows:

Subpart A—General provisions, establishment of the Medicare Advantage Program, definitions, types of MA plans, and cost-sharing in enrollment-related costs (user fees).

Subpart B—Requirements concerning beneficiary eligibility, election, and enrollment and disenrollment procedures.

Subpart C—Requirements concerning benefits, access to services, coverage determinations, and application of special benefit rules to PPOs and regional plans.

Subpart D—Quality improvement program, chronic care improvement program requirements, and quality improvement projects.

Subpart E—Relationships with providers.

Subpart F—Submission of bids, premiums, and related information and plan approval.

Subpart G—Payments for MA organizations.

Subpart I—Organization compliance with State law and preemption by Federal law.

Subpart J—Special rules for MA regional plans, including the establishment of MA regions, stabilization fund, and risk sharing.

Subpart K—Application and contract requirements for MA organizations.

Subpart L—Effect of change of ownership or leasing of facilities during term of contract.

Subpart M—Beneficiary grievances, organization determinations, and appeals.

Subpart N—Medicare contract determinations and appeals.

Subpart O—Intermediate sanctions. Each of these subparts is discussed below in section II of this preamble.

II. Analysis of and Responses to Public Comments

A. Overview

1. Comments on the August 3, 2004 Proposed Rule

We received 186 items of correspondence containing more than a thousand specific comments on the August 3, 2004 proposed rule. Commenters included MCOs and other industry representatives, representatives of physicians and other health care professionals, beneficiary advocacy groups, representatives of hospital and other providers, insurance companies, employers, States, accrediting and peer review organizations, members of the Congress, Indian Health Service (HIS), Indian Health Service, Tribal and Urban Health Programs (I/T/U), American Indians and Alaska Natives (AI/AN), and others. Consistent with the scope of the August 3, 2004 proposed rule, most of the comments addressed multiple issues, often in great detail. We received many comments expressing concerns unrelated to the proposed rule. Some commenters expressed concerns about Medicare unrelated to the MA program, while others addressed concerns about health care and health insurance coverage unrelated to Medicare. Because of the volume of comments we received in response to the August 3, 2004 proposed rule we will be unable to address comments and concerns that are unrelated to the proposed rule. Listed below are the six areas of the proposed regulation that generated the most concern:

- Bidding and Payment.
- Access issues, including network adequacy and access providers, including rural providers.
- Specialized Medicare Advantage Plans.
- Establishment of MA Regions.
- Eligibility and enrollment issues, including disenrollment for failure to pay cost sharing and lock in.

In addition, we received many comments on the proposed rule relating to Part 417 for Health Maintenance Organizations; Competitive Medical Plans, and Health Care Prepayment Plans that contract with CMS under cost contracts. A discussion of those comments may be found separately at that Part.

2. Organization of the Final Rule

In this final rule, we address all comments received on the proposed rule. We are addressing issues according to the numerical order of the relative regulation sections.

B. General Comments

1. Administrative Procedure Act (APA) Issues

We received several comments on various aspects of the rulemaking process, as discussed below:

Comment: One commenter suggested that we waive the APA provision that requires at least 30 days notice prior to a final regulation becoming effective in order to allow applicants applying to become specialized MA plans for special needs individuals, or ''SNPs,'' to have the new requirements apply as soon as possible. The commenter made this recommendation in the event that this final regulation was not issued prior to the MMA statutory deadline for issuing a final regulation for SNPs that was 1 year following the date of enactment, or December 8, 2004.

Response: The first two categories of special needs individuals, institutionalized persons and dual eligibles, were specified in the statute, and we have already begun working with plans wishing to become specialized MA plans for these categories of special needs individuals. We discuss in subpart A below our approach to allowing for the additional category of special needs individuals—those with severe or disabling chronic conditions. This final rule will take effect March 22, 2005, *except where otherwise noted*. We do not believe it is necessary to waive the 30-day notice period because it likely will take longer than the 30-day period for a plan's application and approval process to occur. However, we intend to work with applicants who wish to offer specialized MA plans to ensure that the approval process is as efficient and timely as possible.

Comment: We received a number of comments on the timing of the regulation and the short timeframe between issuance of the final regulation and preparation of applications and bids early in 2005 for contract year 2006. One commenter stated that the time required to re-contract with its commercial provider networks to ensure that the PPO contracts contain the Medicare required language and rate structure that are reflective of CMS reimbursements, is substantial. The commenter indicated that it needed more time to build the system infrastructure to support a new systems platform than would be required for commercial enrollees. The commenters suggested that plans may have to limit the number of regions in which they participate because of the short timeframes between issuance of the regulation and the application filing deadline.

Response: We agree that working within the statutory constraints of the MMA, including the relatively short period of about 13 months between enactment of the legislation and issuance of final regulations, there is little time between issuance of the regulation and the preparation of applications and bids in 2005 for contract year 2006. With respect to the short time frame in applications and submission of bids, please refer to the comments and responses related to bidding at § 422.254 and § 422.502 related to application requirements. Our goal beginning on the date of enactment of the MMA was to issue final regulations as soon as possible so that prospective MA plans would have the necessary information to be able to make business decisions before bids are due mid 2005.

Comment: Several commenters recommended that CMS issue a final rule with comment period prior to implementation of the final rules. The commenters expressed concern that certain aspects of the proposed rule that would impact rural providers have not been specified in sufficient detail. One commenter recommended that CMS conduct a second notice of proposed rulemaking incorporating changes from the first round of comments and allowing for public comment on the additional details that are currently under development, or issue the regulations on an interim basis with a second comment period on the additional, important details that are currently under development or that reflect decisions made following this round of comments.

Response: Under the APA, we are required to provide the public with the opportunity to review and comment upon proposed regulations. We have done this through the publication of the August 3, 2004 proposed rule and its corresponding comment period. We believe that allowing for a second round of comments or publishing interim regulations would make it difficult for MA organizations wishing to offer MA plans in 2006 to prepare to meet the new requirements imposed by the MMA and implemented by this final rule.

2. Other General Comments

Comment: A number of commenters stated that the final regulation must

address the unique state of AI/AN people and the Indian health program. In particular, these comments raise concerns about the implications of the proposed rules on the Indian health care delivery system. For example, there is concern that the proposed rules will jeopardize significant revenues the Indian health system now collects from Medicaid for ''dual eligibles,'' that is, those individuals who are eligible for both Medicare and Medicaid. They ask for substantial modifications to the proposed rules to enable voluntary enrollment by AI/AN populations in MA plans. Some of the suggested modifications include: (1) encouraging MA enrollment by AI/AN by removing financial barriers, such as waiving AI/AN cost sharing for all plans; (2) ensuring that I/T/U Health Programs are held harmless financially, and are fully reimbursed for covered services provided to AI/AN who enroll in a MA plan.

Response: We appreciate the numerous comments that provided information on unique health needs for the AI/AN populations. As noted elsewhere, we are implementing the MMA statute through this rulemaking. We do not have the flexibility to include language that would carve out a subset of Medicare beneficiaries, such as AI/AN populations, if it is not provided for in statutory language. Specific comments raised by the AI/AN and I/T/U organizations will be addressed in the respective subparts under which the comments were submitted. In general, however, we believe that the newly created regional plans will create new choices for the AI/AN populations, and that access to MA plans will be improved. Similarly, because MA regional plans must reimburse for all covered benefits in and out of network, IHS facilities may receive reimbursement for out of network care provided to a regional MA plan AI/AN beneficiary by that MA regional plan. Under provisions designed to protect the Medicare program from fraud and abuse, a broad waiver of beneficiary cost sharing of the type the commenter requests would not be permitted. However, we make no statement regarding the applicability of existing statutory and regulatory provisions that may allow for the waiver of cost sharing in certain cases.

Comment: One commenter recommended that CMS develop and conduct educational and informational activities on the differences in the various MA options, particularly in areas where there are choices of original Medicare, managed care plans, PPOs, MSAs and PPFs plans. The commenter believes that there is a potential for confusion and error for beneficiaries with so many choices.

Response: We agree that strong outreach to beneficiaries about their new choices of MA plans, as well as the drug benefit, is critical to the success of these new programs. We will be devoting more resources to providing new information and education on the new plan choices and drug benefit.

Comment: We received a number of general comments on specialized MA plans for special needs individuals, sometimes referred to as ''SNPs'' or ''special needs plans''. Comments relating to definitions of SNPs may be found in subpart A and comments on enrollment may be found in subpart B below. Among the general comments was a suggestion to disseminate a set of guiding principles for SNPs and further refine them as experience increases. We also received a comment that network adequacy for SNPs should be evaluated to ensure timely, accessible, and appropriate care and that all necessary specialists are represented. Further, it was suggested that the provider network should be broad enough to ensure that vulnerable populations served have timely access to all necessary specialists required to address special needs.

Additionally, several commenters stated that CMS should incorporate into regulation the authority to waive or modify MA requirements that conflict with the intent of the SNP provision. Finally, some commenters requested that CMS provide guidance with regard to the States' role in developing and approving SNPs for dual eligibles. It was recommended that CMS give states maximum flexibility in using waiver authority to integrate Medicare and Medicaid benefits for dual eligibles under SNP programs. A commenter suggested that CMS consult with State Medicaid agencies where Home and Community-based waivers are operating before allowing these populations to be enrolled in SNPs because this could add to the cost and complexity of providing services.

Response: We provided Interim Guidance for SNPs in the 2005 Call Letter in June 2004 and will provide additional operational guidance for SNPs after publication of the final rule. Interim guidance may be obtained at *www.cms.hhs.gov/healthplans/specialneedsplans/qaspecneeds06-23.pdf*. Consistent with current policy for network adequacy for MA plans as found at § 422.112, we will require that MA organizations submit information about their provider network and will review this information as part of the application and approval process to ensure that timely, accessible, and appropriate care is provided. We will be particularly interested in the availability of care designed to address the needs of the enrolled special needs population. While the MMA allows SNPs to limit enrollment to a defined population, as described in § 422.52, the law does not provide for waiver of other MA requirements for SNPs. We encourage States and MA plans to work cooperatively in developing programs to serve dual eligibles and will help to coordinate these efforts where appropriate. We believe that SNPs can be appropriate for care and services to those in the community and lead to the coordination of the complex services they need.

Finally, we note that program oversight is an essential government function that is an integral component of implementing the MA program. Throughout this rulemaking, we refer to government activity necessary to implement this section, which includes program oversight authority.

III. Provisions of the Proposed Rule, Analysis of and Responses to Comments on the Proposed Rule, and Final Decisions

Part 417—Health Maintenance Organizations, Competitive Medical Plans, and Health Care Prepayment Plans

Subpart J–Qualifying Conditions for Medicare Contracts Extension of Reasonable Cost Contracts (§ 417.402)

Authority for cost HMOs/CMPs (cost plans) was due to expire on December 31, 2004. Section 234 of the MMA provides an initial extension of cost plans through December 31, 2007. It also provides for a continued extension of cost plans beyond December 31, 2007, under specific conditions.

Effective for contract years beginning on or after January 1, 2008, cost plans may be extended where there are fewer than two coordinated care plan-model MA plans of the same type available to Medicare beneficiaries in the same service area. Both of the ''competing'' MA plans of the same type must meet minimum enrollment requirements for the entire previous year in order to trigger mandatory cost plan non-renewal or service area reduction. We interpreted the statute to require cost plan service area reduction where there are two or more MA plans of the same type meeting minimum enrollment requirements competing for Medicare members in a portion of the cost plan's service area. We asked for comment on our interpretation in the proposed rule related to mandatory service area reductions, saying that an alternative

reading of section 234 of the MMA might permit renewal of a cost plan in all parts of its service area until there was competition from two (or more) MA coordinated care plans throughout the cost plan's service area. After reviewing comments and responding (below), we are adopting the proposed policy as final.

At § 417.402, we proposed to permit existing cost plans to expand their service areas through September 1, 2006. Thereafter, service area expansion applications by cost HMOs/CMPs will be initially evaluated and accepted only when there are not two or more MA plans of the same type meeting minimum enrollment requirements in the area in which the cost plan proposes to expand. After reviewing comments and responding (below), we are adopting the proposed policy as final.

We received the following comments on the proposed provisions for subpart J of part 417 and have provided our responses:

Comment: Many commenters supported the non-renewal of cost HMOs/CMPs as proposed in the proposed rule. These commenters made reference to the statutory and Conference Committee Report language that indicated the Congressional intent that cost plans are to be required to operate under the same provisions as other private plans to the extent other private plans are willing to enter the cost plan's service area. Many other commenters objected to the partial non-renewal proposal made in the proposed rule. Many stated that competition from MA coordinated care plans was more likely in urban areas, where most cost plan enrollment is concentrated. These commenters stated that even where there is no MA coordinated care plan competition in rural areas, the viability of a cost plan without an urban ''core'' would likely be threatened. To the extent CMS non-renewed cost plans in urban areas, the financial viability of the organization offering the cost plan would be undermined in rural areas as well because of the loss of economies of scale. Such a result would be contrary, these commenters said, to an underlying concept of the MMA, which is to increase choices for Medicare beneficiaries in rural areas. Finally, many of these commenters stated that continuity of care would be needlessly lost for members in urban areas enrolled in cost plans that were partly non-renewed, because the members would be forced to change Medicare plans and providers.

Response: We generally support the notion of continuity of care. However, we believe that when competing MA coordinated care plans are available in an area that will be non-renewed for a cost plan, non-renewed cost members are able to continue to receive services from current providers through either enrollment in one of the competing MA coordinated care plans or by returning to FFS Medicare. We recognize that when a cost plan is non-renewed in an urban area with MA coordinated care plan competition, the financial viability of the cost plan in rural areas without MA coordinated care plan competition may be undermined. However, we believe that allowing a cost plan to continue to compete for members in areas of MA competition would unfairly undermine the financial viability of the competing MA coordinated care plans. Therefore, we have not modified our regulation. We believe that this interpretation is consistent with the statutory intent that cost plans will not be permitted to compete for new members under different provisions from those applicable to other private plans that have entered the cost plan's service area.

Comment: Some commenters stated that the proposed regulation text at § 417.402(c)(1) and (2) did not specify what kind of ''year'' was meant—calendar year, 12 month period, or something else. All of these commenters also recommended that CMS specify in regulation text that the ''year'' referred to is a calendar year.

Response: We agree with this comment and have modified the regulation text to specify that the ''year'' in question is a calendar year. This is consistent with the statute, in that MA and cost plan offerings are for calendar years. To the extent that competition has been present for the entire previous calendar year, it should mean the calendar year immediately prior to the year in which the cost plan will be required to non-renew in a portion of its service area or have its contract non-renewed.

Comment: Many commenters recommended that CMS distinguish between the meaning of ''plan'' within the section 1876 cost program and the meaning of ''plan'' within the MA program. Under the section 1876 cost program, each CMS-contracting HMO/CMP is allowed to offer a single Medicare cost ''plan''—see section 1876(c)(2)(A)(I) of the Act. On the other hand, under the MA program, each CMS-contracting MA organization is permitted to offer many MA ''plans''—see § 422.4(b).

Response: We disagree with the commenters. Section 234 of the MMA expressly provides that a cost contract may not be extended or renewed for a service area if such service area during the previous year was within the service area of two or more coordinated care plans of the same type (that is, regional or local) that meet the relevant enrollment requirements. Because a single MA organization may offer two different MA coordinated care plans within a cost plan's service area, a single MA organization can trigger the non-renewal of the cost contract, if the other requirements of Section 1876(h)(5)(C)(ii) of the Act are met.

Comment: Several commenters submitted comments stating that specialized MA plans for special needs individuals (special needs plans or SNPs) (defined at § 422.2) should not count in the MA coordinated care plan competition tests in § 417.402(c)(1) through (3), because they are not available to the general public and therefore not a true test of the availability of MA coordinated care plans in the service area of a cost plan.

Response: We agree with the commenter that the Congress intended to permit cost plans to remain in place in an area until the enrollees in that cost plan have at least two local or two regional MA plan options to choose from in the area. Because in many cases cost enrollees would not be eligible to enroll in a SNP, we do not believe that the existence of a SNP in a service area should automatically count as an option available in that service area. We note that the statute refers to a cost plan's service area being within the ''service area'' of two local or regional MA plans. The MA regulations at § 422.2 define a plan's service area as an area within which an MA-eligible individual may enroll in a particular MA plan offered by an MA organization. Although a SNP's service area is open to all individuals in the service area who are in the special needs category served by the plan, it may not be open generally to MA-eligible individuals (for example, if it is a SNP that exclusively, rather than disproportionately, enrolls special needs individuals). For this reason, we believe that a cost plan may not be ''within the service area'' of a SNP, as this term is used in the competition test, in some cases. We will therefore apply the competition test on a case-by-case basis with respect to SNPs. If the SNP is an option available to the cost plan's enrollees, and the SNP meets the requirements of section 1876(h)(5)(C)(ii) of the Act and § 417.402(c), it will be taken into account in determining whether the cost plan may be renewed. Similar considerations apply to MA plans that exclusively enroll employer/labor group members under authority provided in section 1857(i) of the Act

and § 422.106(c) and (d). To the extent the employer/labor group MA plan is available to the cost plan's enrollees, and the MA plan meets the requirements of section 1876(h)(C)(ii) of the Act and § 417.402(c), it will be taken into account in determining whether the cost plan may be renewed. Thus, we will also apply the competition test on a case-by-case basis with respect to employer/labor group MA plans.

Comment: One commenter suggested that implicit in the ''competition'' tests was the fact that the MA coordinated care plans that caused the non-renewal in a portion of the service area, or that caused the non-renewal of the cost plan in its entire service area, would be available in the coming year. The commenter was concerned that CMS might enforce this section of the cost regulations, even if one of the MA plans used in establishing the ''competition'' threshold were non-renewing or withdrawing from the service area in the year in which enforcement would occur.

Response: Because such a result would be contrary to statutory intent, CMS will not proceed with enforcement when fewer than two MA coordinated care plans will be offered to Medicare beneficiaries in the affected area at the time of enforcement.

Comment: One commenter asked CMS to state its clear intent in regulatory text that we will allow cost plans to expand service areas after September 1, 2006.

Response: As we said in the preamble of the proposed rule and repeated in this preamble: ''We will permit existing cost plans to expand their service areas through September 1, 2006. Thereafter, service area expansion applications by cost HMOs/CMPs will be initially evaluated and accepted only when there are not two or more MA plans of the same type meeting minimum enrollment requirements in the area in which the cost plan proposes to expand.'' We specifically included the first sentence in regulation text at § 417.402(b). However, service area expansions are not guaranteed after that date. Please note that the regulation text at § 417.402(b) specifically authorizing service area expansions through September 1, 2006, does not preclude them thereafter. Additionally, the new language replaces identical language in this section of the regulation (and which language first appeared in section 634 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA)) which provided service area expansion authority for cost plans through September 1, 2003. The commenter should note that we have previously interpreted the language in BIPA and in our regulations to be permissive in this area, rather than proscriptive. We will continue to apply it permissively in this area to the extent that the conditions for non-renewal under Section 1876(h)(5)(C) and § 417.402(c) are not present.

Subpart Q—Beneficiary Appeals

Changes to subpart Q are addressed in the preamble discussion for subpart M, which deals with appeals policy for MA plans, cost plans and HCPPs.

A. Subpart A—General Provisions (§ 422.1)

1. Conforming Changes

Subpart A of the August 3, 2004 proposed rule set forth several general and conforming changes dictated by MMA. Below is a summary of the provisions in subpart A. (For a broader discussion of the provisions, please refer to our proposed rule.) The provisions are as follows:

- Section § 422.1 lists the statutory authority that is implemented in part 422. In § 422.1, we have added the new section 1858 of the Act that pertains to ''Special rule for MA Regional Plans.''
- We removed provisions relating to application requirements and evaluation and determination procedures in § 422.6 and § 422.8 and added them to § 422.501 and § 422.502 of subpart K, so that all application and contracting information is in one place.
- We redesignated and amended § 422.10 as § 422.6 and amended newly redesignated § 422.6. Section 422.6 (formerly § 422.10) described the user fees associated with the Medicare Beneficiary Education and Information Campaign, required under section 1857(e)(2) of the Act.

2. Definitions (§ 422.2)

The majority of the proposed changes in subpart A concerned new, revised, and obsolete definitions for the new MA Program in § 422.2. The MMA required several new and broad definitions; ''MA regional plans,'' ''specialized MA plans,'' ''ACR,'' ''Additional benefits,'' ''Adjusted community rate,'' and ''M+C'' obsolete after 2006.

In proposed § 422.2, we also revised several existing definitions to make them consistent with the MMA statute. For example, Mandatory supplemental benefits are redefined to incorporate language reflecting that these benefits may be paid for through premiums and cost sharing or through the application of a rebate, or both. Therefore, mandatory supplemental benefits are defined as health care services not covered by Medicare that an MA enrollee must purchase as part of an MA plan. Benefits may include reductions in cost sharing for benefits under the original Medicare FFS program, and are paid for in the form of premiums and cost sharing, or by an application of the beneficiary rebate rule in section 1854(b)(1)(C)(ii)(I) of the Act, or both.

However, optional supplemental benefits retained the same definition as under the M+C program as health services not covered by Medicare that are purchased at the option of the MA enrollee and paid for in full, directly by (or on behalf of) the Medicare enrollee, in the form of premiums or cost-sharing. (Throughout the regulation, the phrase ''supplemental benefits'' refers to both mandatory and optional supplemental benefits.) The terms ''mandatory supplemental'' and ''optional supplemental'' are used when referring specifically to one of the types of supplemental benefits.

We removed ''additional benefits'' from the definition of ''basic benefits'' because MA plans will no longer offer additional benefits. In addition, we replaced the word ''ACR'' process with the words ''annual bidding'' process in the definition of ''benefits'' to reflect the new bidding process for submission and approval of benefits. Finally, we revised the definition of ''service area'' to incorporate the concept of the new MA regional plan's service area that consists of an entire region.

Under section 1851(a)(2)(A) of the Act, two new types of coordinated care plans were established; MA Regional plans, which are regional PPO plans, and specialized MA plans for special needs individuals, or SNPs. We defined an ''MA local area'' as a county or other area specified by us because it is important to distinguish an MA local area from an MA region. We defined an ''MA regional plan'' because it is a new type of coordinated care plan choice for beneficiaries. While PPOs first became a choice for beneficiaries under the BBA, they operated as ''local'' plans on a county (including multi-county) or partial county basis. The MA regional plan functions like a local PPO but must serve an entire region.

A regional MA plan's service area is one or more entire MA regions; thus, we defined an ''MA regional plan'' as a private health plan that operates as a PPO, but serves an entire CMS-designated region. Local PPOs that may offer MA plans under the MA program, the regional PPOs must have a network of contracting providers that have agreed to a specific reimbursement for covered benefits that are offered by the MA regional plan, and must also provide for reimbursement for all

covered benefits regardless of whether the covered benefits are provided through the network providers or outside of the network.

We defined an ''MA local plan'' as one that is not an MA regional plan. Also defined under part 422 are the ''Prescription Drug Sponsor,'' ''PDP,'' and a ''MA Prescription Drug (MA-PD) plan.'' A sponsor must be a private entity that meets our requirements and standards. PDP sponsors may offer multiple plans throughout the country or in a region, but sponsors must submit an individual bid for each plan.

An MA-PD plan is an MA plan that also provides qualified prescription drug coverage as found in Part D of the Act. An organization offering a coordinated care MA plan must have an MA-PD plan in each of the service areas in which it operates, as required under section 1860D 21(a)(1) and (2) of Part D of the Act.

In section 1859(b)(6)(A) of the Act, specialized MA plans for special needs individuals or SNPs are defined to be MA plans that exclusively serve special needs individuals defined in section 1859(b)(6)(B) of the Act. The establishment of specialized MA plans allows MA plans to exclusively enroll special needs individuals in MA plans that have targeted clinical programs for these individuals.

Section 1859(b)(6)(B) of the Act identifies three types of special needs individual as: (1) institutionalized individuals; (2) individuals entitled to medical assistance under a State plan under Title XIX; and (3) other individuals with severe or disabling chronic conditions as the Secretary determines would benefit from enrollment in a SNP plan.

Comment: One commenter supported a broad definition that tracks section 1859(b)(6) of the Act in order to provide CMS with the flexibility needed to approve a wide range of proposals to meet the unique needs of special populations and expand their choices.

Response: We agree with the commenter. We are providing general guidelines in our regulations in order to maintain the flexibility to approve a wide range of proposals, while also protecting the interests of special needs beneficiaries.

The Secretary may also designate an MA plan as a specialized MA plan for special needs individuals, ''SNP,'' if the plan ''disproportionately'' serves special needs individuals.

Comment: Several commenters responded to the question in the proposed rule as to whether CMS should allow specialized MA plans that disproportionately enroll special needs individuals, or ''disproportionate percentage'' plans and how they should be defined. Most commenters supported including ''disproportionate percentage'' plans in the definition of SNPs. One of the reasons given was to allow married beneficiaries, or children of special needs individuals, to enroll in the same plan as the spouse or parent, even if only one individual meets the definition of a special needs individual.

Many commenters suggested that CMS not establish detailed criteria to define disproportionate percentage, particularly at the outset. It was felt that enrollment thresholds might act as a barrier to plan participation and limit choices available to Medicare beneficiaries. Some commenters suggested that CMS identify ''exclusive'' and ''disproportionate'' plans at the time of each application. Some commenters recommended that the criteria be national, not regional or local.

Several commenters agreed that the criteria should be quantitative, for example, an MA plan risk score in the upper quintile of all MA plans, or a frailty score in the upper quintile of all MA plans as measured by Activities of Daily Living (ADL) scores on the Health Outcomes Survey (HOS).

Some commenters recommended that a ''disproportionate percentage'' SNP enroll fifty (50) percent or more special needs individuals. Another commenter suggested that SNPs remain exclusive, but if plans were able to enroll those without special needs, at least eighty-five (85) percent of the plan's enrollees should be individuals with special needs. Another commenter stated that requiring an upper limit of more than seventy-five (75) percent of special needs individuals would be problematic. One commenter believes that ''redesignated'' SNPs, that is, regular MA plans that become SNPs, be allowed to continue enrolling non-special needs individuals as long as overall enrollment contains a higher proportion of special needs individuals than exist in the plan's service area. One commenter suggested that—(1) an annual certification and compliance process; (2) that new plans have a 3-year startup period to attain the threshold, and (3) that CMS annually publish risk score distributions. Another commenter recommended that non-exclusive plans be defined as having a higher than average enrollment of one or more of the special needs individuals groups as estimated for MA plans and/or the FFS population.

Response: We agree that a special needs individual's family members may want to join the same plan. We acknowledge that MA plans do not have to be exclusive to provide quality specialized programs for special needs individuals. We received a wide range of recommendations for defining a ''disproportionate percentage'' SNP. We acknowledge that there are numerous ways to define and identify disproportionate percentage SNPs and agree with those commenters who felt the parameters should not be overly restrictive, particularly at the outset. SNPs are a new type of coordinated care plan and we believe that plans and CMS might not anticipate all factors that should be considered in determining an acceptable percentage. We also want to encourage plans to develop programs to more effectively care for special needs individuals. In order to ensure flexibility, and take into consideration the experience gained by plans and CMS as SNPs mature, we will define a ''disproportionate percentage'' SNP as one that enrolls a greater proportion of the target group (dually eligible, institutionalized, or those with a specified chronic illness or disability) of special needs individuals than occur nationally in the Medicare population based on data acceptable to CMS. We will provide further guidance as to what data sources may be used to determine a national percentage for a special needs group being targeted by the disproportionate percentage plan. Under our authority as provided in section 231(d) of the MMA, we are revising the definition of specialized MA plan to include ''disproportionate percentage'' plans.

Comment: Several comments were received regarding how CMS should identify those with severe or disabling chronic conditions that would make them eligible for enrollment in a SNP. Several commenters suggested using broad flexibility, reflecting the language in section 1858(b)(6) of the Act. Other commenters recommended that SNPs should serve as laboratories for developing population-based management protocols, not single-disease State management protocols for diagnoses that could be well-served by a standard MA plan. Another commenter recommended limiting enrollment to those with late-stage chronic conditions, those with co-morbidities, adult disabled, and frail elderly. Some commenters suggested basing the definition on conditions for which alternate care delivery models, such as disease management and evidence-based medicine, exist, and also take into consideration conditions that are expensive and prevalent for

there to be savings and risk-management potential.

Commenters also recommended that conditions should be those associated with recognized quality measures, so that CMS may carefully monitor specialized MA plans. None of the commenters objected to including those individuals who are not institutionalized but require an equivalent level of care. ESRD, diabetes, congestive heart failure, Alzheimer's and other dementias along with one or more other serious conditions, HIV/AIDs, and frail elderly and adult disabled with multiple chronic conditions requiring complex medical management were among the specific conditions suggested for specialized MA plans.

Another commenter suggested that on an interim basis CMS restrict the definition to those who are nursing home certifiable, as defined by each State; ESRD patients; and those diagnosed with AIDs, and, in the meantime, collect ADL data through the Health Outcomes Survey (HOS) and use this measure in conjunction with Activities of Daily Living (ADL) measures to identify high-risk groups. Other commenters suggested additional detailed formulas for identifying groups eligible for specialized MA plans.

Response: Because this is a new ''untested'' type of MA plan, we are not setting forth in regulation a detailed definition of severe and disabling chronic condition that might limit plan flexibility. We will review and evaluate proposals for specialized MA plans that serve severe or disabling chronic disease categories, including HIV/AIDs, on a case-by-case basis. Among the criteria to be considered will be the appropriateness of the target population, the existence of clinical programs or special expertise to serve the target population, and whether the proposal discriminates against ''sicker'' members of the target population.

Other Comments on § 422.2

We requested comments on § 422.2 on the development of an HIV/AIDS special needs plan that would address the special health needs, including prescription drugs, of the Medicare-eligible population living with HIV/AIDS.

We received several comments supportive of the development of an HIV/AIDS special needs plan. Therefore, we will consider this type of plan application to become a special needs plan for Medicare-eligible individuals living with HIV/AIDs.

For purposes of specialized MA plans, we proposed to define ''institutionalized'' in the proposed rule as residing in a long-term care facility for more than 90 days as determined by the presence of a 90-day assessment in the Minimum Data Set (MDS).

Comment: Several commenters suggested that the 90-day residence requirement (as determined by a 90-day assessment in the minimum data set) be modified. One commenter suggested determining institutional status based on the discharge potential at admission. Another commenter suggested changing the requirement to 30 days. One commenter did not object to 90 days, but recommended changing the language to allow CMS to approve exceptions in case the institution failed to perform the assessment. In addition, one commenter suggested that ''institutionalized'' also include those residing in Intermediate Care Facilities for the Mentally Retarded (ICF/MR). Several commenters recommended that those living in the community while requiring an institutional level of care be considered institutionalized.

Response: In response to comments, we are clarifying and broadening the definition of institutionalized for purposes of defining a special needs individual to take into consideration those with chronic mental conditions and other chronic conditions. For purposes of defining a special needs individual, ''institutionalized'' means residing in or expected to reside in a long-term care facility which is a skilled nursing facility (SNF) as defined in section 1819(a) of the Act; a nursing facility (NF) as defined in section 1919(a) of the Act; a SNF/NF; an intermediate care facility for the mentally retarded (ICF/MR) as defined in section 1905(d) of the Act; or an inpatient psychiatric facility as defined in section 1861(f) of the Act for 90 days or longer.

A SNP may enroll special needs individuals prior to a 90-day stay based on an assessment of the potential for a stay of that length as long as the assessment is of a type approved by CMS.. For example, a SNP for individuals with serious mental conditions may show us that the State requires a plan of care or similar assessment prepared by a health professional upon admission. We recognize that this definition is not the same as the definition of ''institutionalized individual'' in 42 CFR § 423.772. That provision is an income and resource-based definition for the purpose of determining Part D premiums and cost-sharing subsidies for low-income individuals. The term ''institutionalized'' as used for purposes of defining a special needs individual under this Part is for the purpose of identifying a vulnerable population that might benefit from enrollment into a SNP. We also wish to clarify that our definition of institutionalized for purposes of defining a special *needs individual does not relate to the MA payment methodology*.

For purposes of SNPs, we may also consider as institutionalized those individuals living in the community but requiring a level-of-care equivalent to that of those individuals in the aforementioned long term care facilities. We believe that 90 days is the most appropriate and accurate timeframe for determining long-term residence in an institution. We base this on information we collected showing that, once a beneficiary is institutionalized for 90 or more days, it is less likely that that individual will return to a community setting. However, SNPs may enroll institutionalized beneficiaries based on a CMS-approved assessment (as described in further operational guidance following publication of this rule) showing the beneficiary is expected to reside in the institution for 90 days or more. Given the latitude provided under the disproportionate percentage criteria, we do not think that the 90-day definition for institutionalized will adversely affect specialized MA plans' ability to enroll eligible beneficiaries.

Comment: Several commenters supported the proposed approach to require all specialized MA plans to provide Part D coverage.

Response: We agree with the commenters, especially in light of the fact that special needs individuals in particular need access to prescription drugs to manage and control their severe or disabling chronic conditions. Therefore, we are including the Part D coverage requirement for all specialized MA plans at § 422.2 in the definition of a specialized MA Plan.

Comment: One commenter recommended that CMS change the definition of PDP as it is incorrect and not consistent with the Medicare Prescription Drug Benefit Program proposed rule.

Response: We agree with the recommended change to the definitions of PDP and PDP sponsor found at § 422.2. To avoid any confusion, we are revising the definitions in Title II to cross-reference the definitions of PDP and PDP sponsor found in part 423, the Medicare Prescription Drug Benefit.

Comment: Several commenters recommended that CMS make a revision to the basic benefits definition found at § 422.2 to add ''including covered services received through an IHS

program.'' Other commenters recommended that CMS add to the special needs individual definition ''AI/IN are exempt from mandatory enrollment in Title XIX plans but would qualify for optional enrollment in an AI/AN specialized need plan.''

Response: We do not believe there is a statutory basis in the MMA to include non-covered Medicare services received through an IHS program in the definition of basic benefits. We also do not believe it is necessary to include a specific reference to Medicare covered services provided through an IHS program in the definition of basic benefits. If a service is a covered service, it is already included in the definition. Therefore, we are not making the requested change. Similarly, the MMA does not authorize us to revise the definition of special needs individual as suggested. The statute defines special needs individuals who are defined as those who are Medicaid, institutionalized or those with severe or disabling chronic conditions. Clearly, AI/AN individuals who fit any of those definitions could choose to enroll in a specialized MA plan if one were offered in their area. The suggested change to the definition of special needs individuals to add optional enrollment in an AI/AN specialized MA plan suggests that some AI/AN organizations may be interested in offering a specialized MA plan. Under the statute, a specialized MA plan must be open to all eligible Medicare beneficiaries who are within the class of special needs individuals the plan serves. We see no statutory basis for allowing a plan to limit enrollment only to AI/AN Medicare beneficiaries. Conceptually, supplemental benefits could be offered in the specialized MA plan to assist chronically ill enrollees to prevent or treat illnesses that affect AI/AN populations and others enrolled in the plan. As described at § 422.501, a prospective SNP would need to submit an application to CMS detailing its plan for treating those with severe or disabling chronic conditions. Finally, we would note that we are not adding language exempting AI/AN from mandatory enrollment in Title XIX plans as it is not within the scope of this rulemaking. We note however, that under sections 1115 and 1915(b) of the Act, mandatory enrollment under Medicaid for such populations is permitted.

Comment: Several commenters suggested that CMS add a new definition to § 422.2 to afford specialized MA plans the status of regional MA plans for most purposes (including special rules and incentives applicable to regional MA plans), without having to cover multiple States. The commenters suggested that plans may be reluctant to take on multiple State regions with enrollment limited to Medicaid eligibles in the region.

Response: As described in section 1858(a)(1) of the Act and as reflected in § 422.455(a), a MA plan must cover an entire region, including offering enrollment to all eligible Medicare beneficiaries within that region whether the region is a single State or multiple State area. Therefore, a special needs plan may receive the stabilization fund payments and other incentives for its participation as a regional plan only if the plan would comply with all requirements in section 1858 of the Act applicable to Regional MA plans. This means, that it would have to be open to enrollment for every member of the special needs category in the entire region in question, meet access standards for the individuals in all areas of the region, market to all areas of the region, and offer uniform benefits and cost-sharing in all areas of the region.

Comment: A commenter recommended that CMS revise the definition of service area as found in § 422.2. The commenter indicated that as proposed, the language of § 422.2 appears to have established a lower standard for approval of regional PPO service areas. The commenter recommended that CMS separately define service area requirements for HMOs and PPOs and that the requirements for approval of a PPO apply to both local and regional PPO plans alike.

The commenter also recommended that CMS consider the more flexible design of a PPO and in turn allow for more flexibility with respect to service area approval. The commenter understands that local PPOs are not required to cover an entire region, but also indicated that it is difficult even in small States to meet the availability and accessibility requirements by the time the service area application is due.

Response: We appreciated the comment to clarify this definition as we found it had been improperly numbered and created some confusion. Therefore, we have renumbered the sub-definitions and included language that makes clear that we may consider whether the contracting provider network meets the access and availability standards set forth in § 422.112, for all MA coordinated care plans and network MA MSA plans. We also have made technical corrections because the distinction between non-network and network MSA plans is no longer applicable, as discussed in further detail below. We believe this change will further reduce confusion.

3. Types of MA Plans (§ 422.4)

The MA program is intended to provide beneficiaries access to a wider array of private health plan choices than under the M+C program and to increase the number of areas in which private health care options are available to Medicare beneficiaries. Entities can contract with us to provide five general categories or types of plans: (1) local MA coordinated care plans; (2) MA MSA plans; (3) MA PFFS plans; (4) regional PPO coordinated care plans; and (5) specialized MA coordinated care plans.

In the August 3, 2004 proposed rule, we proposed to clarify that the PPO definition that was in existence before (defined by the BBRA) was solely for purposes of the application of the more limited quality assurance requirements. For PPO-type plans that are offered by MA organizations that are licensed or organized under State law as HMOs, the quality assurance requirements that apply to all other coordinated care plans in section 1852(e) of the Act also apply to those PPO-type plans.

Effective January 1, 2006, MA organizations that offer MA local plans that are PPOs will need to provide only for the collection, analysis, and reporting of data that permit the measurement of health outcomes and other indices of quality insofar as services are furnished by providers that have contracted with the MA organization under those PPO plans. However, a local PPO offered by an MA organization that is licensed or organized under State law as an HMO will be required to meet the normal data collection, analysis, and reporting requirements. We proposed to modify the definition of PPOs in § 422.4 to account for this more limited interpretation of State licensure requirements and modified headings in § 422.152(b) and (e).

Under section 233 of the MMA, MA organizations are authorized to offer MSA plans as a permanent option. MMA also eliminated the limits imposed on MSA plans by the BBA, including a time limit on enrollment and a limit on the number of beneficiaries who could enroll in the plans, and exempted MSA plans from certain quality assurance requirements that the BBA applied to ''network'' MSA plans.

To conform with MMA's changes to MSAs, we proposed to delete the descriptions of the M+C network MSA plan and M+C non-network MSA plan as different types of plans at

§ 422.4(a)(2)(ii), since the distinction between network and non-network MSAs for the purpose of quality assurance requirements was no longer applicable. As noted above, we are making similar changes to the definition of service area at § 422.2.

We are making a technical correction to the final MA regulation. Our current regulations at § 422.2 read ''Religious and Fraternal Benefit (RFB) Society.'' We are amending the definition of ''Religious and Fraternal Benefit (RFB) Society'' by removing the words ''Religious and fraternal'' and adding the words ''Religious fraternal'' in their place. We are making this change to the definition as it is potentially confusing and is not consistent with the statutory definition of ''Religious Fraternal Benefit Society'' at section 1859(e)(3) of the Social Security Act. We are also making a technical change to § 422.4(a) to clarify that RFB Society plans may be any type of MA plan, and are not restricted to being a type of coordinated care plan only, as implied by the inclusion of ''RFBs'' exclusively in § 422.4(a)(1)(iii). Thus, we are removing the reference to RFBs from that section. We also are deleting the word ''network'' from the parenthetical at the end of § 422.4(a)(1)(iii) because the distinction between network and non-network MSAs no longer applies.

Comment: Many commenters suggested that CMS more clearly coordinate between the Medicare Prescription Drug Benefit Rule at part 423 and the MA Program Rule at part 422.

Response: In response to this comment, we are making several changes to clarify the interaction between Part C and Part D. Specifically, we are clarifying the language at § 422.4 on types of MA plans and Part D prescription drug coverage. We are adding a new paragraph (c), Rule for MA Plans' Part D Coverage. This paragraph clarifies the requirements for MA coordinated care plans, MA MSAs, and MA PFFS plans by stating that a coordinated care plan must offer qualified Part D coverage meeting the requirements in § 423.104 in that plan or in another MA plan in that area. We also added language that MSAs cannot offer drug coverage, other than that required under Parts A and B of Title XVIII of the Act. Finally, we added language that MA organizations offering PFFS plans can choose to offer qualified Part D coverage meeting the requirement in § 423.104 in that plan.

Comment: One commenter recommended that CMS clarify the language at § 422.4(a)(1)(v). The commenter wants to ensure that an organization that wants to apply as a local HMO, but does not have an HMO license in its State, but is otherwise licensed as a risk-bearing entity in its State, will not be considered a PPO and thus subject to the 2-year moratorium on local PPOs as found at section 221(a)(2) of the MMA and proposed at § 422.451.

Response: We do not believe that a clarification of § 422.4(a)(1)(v) is required as § 422.400 already provides that an MA organization must be licensed under State law, or otherwise authorized to operate under State law, as a risk-bearing entity (as defined in § 422.2) eligible to offer health insurance or health benefits coverage in each State in which it offers one or more MA plans. Therefore, an organization that wishes to apply as a local MA plan HMO and has a State-risk bearing license would be considered an HMO and not be considered as a local MA plan PPO nor subject to the PPO moratorium described at § 422.451. However, a plan would have to market itself as an HMO or an HMO with a POS option. A plan could not market itself as a PPO because of the potential for confusion.

Comment: Several commenters recommended that CMS include new language in the final regulation that ensures that the type of denial of covered services as described in the Government Accountability Office (GAO) report entitled ''Medicare Demonstration PPOs: Financial and Other Advantages for Plans, Few Advantages for Beneficiaries (GAO–04–960)'' never happens again. One commenter, also referring to the GAO report, expressed concern that the Agency is not effectively enforcing current law, based on the recent GAO findings.

Response: In response to the GAO evaluation, we agreed to implement the GAO recommendation for us to instruct Medicare PPO Demonstration plan participants to remove impermissible restrictions on an enrollee's access to providers for all covered plan benefits. We are committed to assuring that local and regional PPOs provide reimbursement for all covered benefits regardless of whether the benefits are provided within the network of providers as found in § 422.4(a)(1)(v).

Comment: Several commenters recommended that CMS require non-contracted providers to accept Medicare fees as payment in full with no balance billing to the beneficiary. The commenters believe that this approach will protect beneficiaries from excessive payment liability for out of network services.

Response: As discussed in further detail in subpart C of the preamble to this final rule, there are several existing limitations on balance billing that apply to protect Medicare beneficiaries regardless of whether they are enrolled in an MA plan. Further, under existing rules, beneficiaries may not be held liable for more than the amount of out-of-network cost sharing for the service specified in the plan. For these reasons, we do not believe the changes requested by the commenter are necessary.

Comment: Several commenters supported the amendment found in the proposed rule that clarifies that a plan licensed as an HMO may still become a PPO under its HMO license as long as the State allows the HMO to offer a PPO under its HMO license. However, the commenters suggested that CMS revise § 422.4(a)(1)(v) in the following two ways: (1) clarify that PPOs may establish before authorization requirements for services obtained out-of-network that would allow for a review based on medical appropriateness; and (2) modify the provision to indicate that PPOs are not obligated to make available out of network certain types of programs, like health and wellness programs, for which no non-network counterpart is available.

The commenters also recommended that CMS clarify that only original Medicare benefits must be covered both in and out of network and that covered benefits that are not part of original Medicare need not be covered out of network. The commenters opposed CMS' requirement that for 2005, PPO plans must offer all benefits both in and out of network. The commenters stated that many plans in the private sector and in the FEHB program limit out-of-network coverage for some services. The commenters believe that requiring coverage of all non-original Medicare benefits in and out of network implies that there is a standard allowance or price reference upon which to base payments for these services. The commenters also suggest that there are no balance billing protections for the beneficiary who seeks care out of network. The commenter expressed similar concerns around the Medicare drug benefit and the lack of specificity regarding coverage of non-original Medicare benefits. The commenter also believe that covering certain benefits out of network (for example, disease management, 24-hour advice nurse lines, and wellness programs) will pose a significant challenge.

Response: To respond to the first recommended change to § 422.4(a)(1)(v)requesting that MA plans be allowed to impose pre-authorization

requirements on out-of-network care by PPOs, section 1852(e)(3)(A)(iv)(II) of the Act states that a PPO plan must provide for reimbursement for all covered benefits, regardless of whether the benefits are provided within the plan's network of providers. Similarly, section 1859(b)(4)(B) of the Act, which defines MA regional PPOs, includes the same requirement to provide for reimbursement for all covered benefits regardless of whether the benefits are provided within the network of providers. These provisions indicate the Congress's clear intent to ensure that PPOs provide coverage for all plan-covered benefits both in and out of network. Further, although other coordinated care plans may include mechanisms to control utilization, such as referrals from gatekeepers for an enrollee to receive services within the plan, the definition of PPO contained in sections 1852(e)(3)(A)(iv) and 1859(b)(4)(b) of the Act indicates that local and regional PPOs may not use similar mechanisms, such as pre-authorization, to restrict enrollee access to out-of-network services. However, there are several ways PPOs can appropriately seek to promote the use of in-network services. For example, PPOs may encourage beneficiaries to notify them before seeking care out of network, so that care is coordinated in and out of network. PPO plans may offer incentives to beneficiaries to provide notice of their intent to seek out-of-network services by discounting out-of-network cost sharing when beneficiaries provide notice before receiving services. Further, MA organizations are required to have procedures for making determinations of whether an enrollee is entitled to receive a health service and the amount that the enrollee will be required to pay for the service. Thus, a PPO plan enrollee and provider may seek an advance determination of coverage before receiving the service, and we encourage PPO enrollees to avail themselves of this option.

On the commenters' request to clarify in § 422.4(a)(1)(v) that only original Medicare benefits must be covered in and out of network, we believe that the clear language in the statute at section 1859(b)(4)(B) of the Act relating to regional MA plans and section 1852(e)(3)(A)(iv)(II) of the Act relating to local PPOs, does not permit us to limit the requirement that PPOs provide for reimbursement for all plan-covered benefits both in and out of network. Therefore, we are not modifying the definition of PPOs at § 422.4(a)(1)(v). However, to respond to some of the concerns raised in the comment, we again note that plans can reduce the regular cost sharing for out-of-network benefits for beneficiaries who voluntarily seek pre-authorization for those benefits. As described by another response to comment above, we disagree with the commenter that there are no balance billing protections for beneficiaries. There are limitations on balance billing to protect beneficiaries regardless of whether they are involved in an MA plan or not. Finally, on the issue of benefits, such as nurse advice lines, which plans believe should not be made available out of network, we believe that as a practical matter, most of these types of benefits will be unattainable out of network because they are designed to be provided exclusively to plan members. Additional discussion of these types of out-of-network benefits can be found in the subpart C preamble.

Comment: Comments were received on § 422.4(a)(1)(v). Several commenters suggested that CMS address perceived inconsistencies in licensing requirements for PPOs as compared to HMOs by confirming the scope of State licensure requirements that apply to entities offering MA PPO plans, as State licensing laws may restrict an HMO's ability to offer a PPO plan.

Response: We do not believe there are inconsistencies. All MA plans must be licensed by the State as a risk-bearing entity. State law controls whether the MA organization is licensed or authorized to offer the type of MA plan it proposes to offer. As we explained in the preamble discussion in subpart A of the proposed rule, the fact that MA organizations offering local PPOs that are (or are not) licensed as HMOs is pertinent to the MA program solely for purposes of the application of quality improvement standards in section 1852(e) of the Act, and has no specific bearing on whether an MA organization has State authority under applicable State law to offer an HMO or PPO under the MA program. Whether an MA organization (licensed either as an HMO or otherwise) can offer a specific type of MA plan continues to rest upon whether the organization has State licensure or authority to offer such a type of MA plan.

Comment: One commenter requested that CMS consider enabling the PFFS model as an option under the regional preferred provider organization structure. The PFFS model in the MA program enables broader geographic coverage without the specific provider contracting requirements. This option could expand participation in the regional program by enhancing participation and access in rural areas without specific provider contracting access requirements as is currently available under the existing MA PFFS plans.

Response: Since a PFFS plan is not defined as a type of coordinated care plan under section 1851(a)(2)(A)(i) of the Act, it would not be possible to allow an MA organization to offer a PFFS plan as an MA regional plan. Additionally, MA PFFS plans are defined at section 1859(b)(2) of the Act, while MA regional plans are defined at section 1859(b)(4) of the Act. The definitions are mutually exclusive.

Comment: A few commenters asked whether SNPs could be any type of coordinated care plan.

Response: We believe that section 1851(a)(2)(A)(ii) of the Act clearly states that SNPs can be any type of coordinated care plan.

4. Expansion of the Beneficiary Education and Information Campaign ''User Fees'' (§ 422.6, formerly § 422.10)

The last section of subpart A contained regulations implementing the user fees provided for in section 1857(e)(2) of the Act. MMA expanded the user fee to include PDP sponsors as well as MA plans as contributors. The expansion of the user fee recognizes the increased Medicare beneficiary education activities that we would require around the new prescription drug benefit.

As before, the user fee would pay for the ongoing costs of the national beneficiary education campaign that includes developing and disseminating print materials, the 1–800 telephone line, community based outreach to support SHIPs, and other enrollment and information activities required under section 1851 of the Act and counseling assistance under section 4360 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 103–66).

As indicated in the proposed rule and in this final rule (§ 422.6), in fiscal year 2006 and thereafter, the MMA authorizes up to $200,000,000, reduced by the fees collected from MA organizations and PDP sponsors in that fiscal year. (The total amount is not indexed in any way.) In each year, the total amount of collected user fees may not exceed the estimated costs in the fiscal year for carrying out the enrollment and dissemination of information activities in the MA and Part D prescription drug programs or the applicable portions of $200,000,000, whichever is less.

These user fee provisions establish the applicable aggregate contribution portions for MA organizations and PDP

sponsors. The applicable portion of the user fee for MA organizations will be based on the total proportion of expenditures for Medicare Part C as well as for payments under Part D that are made to MA organizations as a percent of Title XVIII expenditures. The PDP sponsor's applicable portion is the estimate of the total proportion of expenditures under Title XVIII that are attributable to expenditures made to PDP sponsors for prescription drugs under Part D. The fees charged to individual MA plans and PDP sponsors would continue to be determined by CMS. These fees are calculated by a percent of plan's revenue to avoid over-burdening smaller plans.

Comment: One commenter supported CMS' efforts to increase user fees to support beneficiary education. The commenter recommended that CMS collect the entire amount authorized under the statute and work with the Congress to either index it or otherwise lift the cap if needed to adequately inform beneficiaries about the new complexities with private plans.

Response: The changes the commenter requested are beyond the scope of this rulemaking. We do not intend for the user fee to be exclusively for education on MA plans. We anticipate that the user fee will also be used on the new Part D drug benefit, which we believe will consume a large portion of the user fees, due to the newness of the benefit.

Comment: Two commenters believe that there is insufficient funding of the SHIP program and recommended that CMS use a portion of the MA and PDP user fees to support SHIPs.

Response: Early in the implementation of the M+C program, SHIPs received some funding from the user fee. However, for the last several years, SHIP funding has been a specific line item appropriation by the Congress. We have some discretion regarding how the user fees are spent in terms of beneficiary education, so it is possible for SHIPs to get some of their funding from the user fee. However, decisions on how to spend user fees are internal management decisions relating to resource allocation, and therefore will not be included in this regulation.

Comment: One commenter recommended that beneficiary educational materials be shared with Congressional committees of jurisdiction prior to releasing them.

Response: The timelines for providing education materials are limited. Although we do not intend to seek Congressional authorization before the release of the education materials, the materials will comply with the provisions of the statute and regulations, and we will make every effort to ensure that they are useful to beneficiaries in making their choices. CMS' Office of Legislation works closely with the Congressional offices to ensure that they are aware of and have open access to copies of various educational materials either before or in the same timeframe as their constituents to help with education and outreach activities.

Comment: One commenter expressed concern that the funds used to educate beneficiaries may be more focused on explaining the array of choices and not focused enough on encouraging beneficiaries to actually make a choice. The commenter encouraged CMS to work directly with experienced plans to conduct information campaigns that result in significant Part D uptake rates for PDPs and MA-PDs. The commenter was concerned that beneficiaries may be confused by the changes beginning in 2006.

Response: We appreciate the commenter's suggestion for us to work with experienced plans to conduct information campaigns that could expand enrollment in MA-PDs and PDPs beginning in 2006 (especially in light of the new options that will be available at that time). We expect to engage a strong network of experienced plans, providers, and other stakeholders and partners to provide input and feedback on beneficiary education plans and to provide specific suggestions on ways to communicate the changes that will occur in the MA program in 2006.

Comment: One commenter believes that CMS will require the resources, both financial and human, to help beneficiaries make choices about benefit and plan options that appropriately reflect their needs and preferences. The commenter recommended that CMS bolster programs such as one-on-one counseling, which beneficiaries prefer, and to design beneficiary materials in formats that make information easy to interpret and understand. The commenter also recommended that CMS create information resources, such as the 1–800 number, but also help beneficiaries understand the information that is being presented.

Response: We agree that we will have to continue to educate beneficiaries on MA program changes in a way that helps the beneficiary to understand the program and understand what type of Medicare plan would best suit his or her individual health and financial needs. We routinely test education and outreach products with beneficiaries during development to ensure that they are broadly accessible and understandable to the appropriate target audiences.

Comment: A commenter indicated that there are high costs to I/T/U for MMA implementation costs related to outreach, education and enrollment of an AI/AN individual. The commenter encouraged CMS to acknowledge the need for funding that is specifically directed to local I/T/U to support these activities where the work is done and where bearing the costs is the most difficult. The commenter believes that unlike other Medicare populations, AI/AN beneficiaries are unlikely to enroll in MA plans without specific information from their I/T/U.

Response: We agree that education and outreach efforts should be tailored to the needs of specific populations interested in enrolling in MA plans, to the greatest extent possible. We will continue our collaboration with the IHS and other partners to identify the most effective ways to reach beneficiaries in the AI/AN population.

Subpart B—Eligibility, Election and Enrollment

We proposed generally to retain the same eligibility, election and enrollment rules that currently apply to the Medicare Advantage program. We received numerous comments on this subpart in response to the August 2004 proposed rule. These comments and our responses are presented below.

1. Eligibility to Elect an MA Plan (§ 422.50)

In this section, we specified the following:

- Reference to an ''MA plan'' includes both MA local and MA regional plans, unless specifically noted otherwise in the text.
- We reserve the authority to allow additional optional mechanisms for elections (for example, website enrollment) to provide a more efficient and simplified election process for beneficiaries and partner organizations.

Comment: Several commenters supported the proposal to retain the authority to allow additional optional MA election mechanisms, stating that this change will promote the development of more efficient and simplified processes for beneficiaries. One commenter requested clarification that any such alternate election mechanism would be optional for individual MA organizations to use. Another commenter supported the change, but stated that CMS should not mandate that MA organizations accept electronic elections.

Response: The revision made to this section is intended only to permit us to

approve alternate optional election mechanisms (in addition to paper election forms) in the future. We anticipate that such mechanisms will be available at the option of each MA organization. Furthermore, we believe it is important to clarify that, as other election mechanisms are approved and implemented, we do not intend to permit MA organizations to require beneficiaries to use any such election mechanism. We will require all MA organizations to establish a minimum standard process, which, at this time, will be a paper process, and will be made available to prospective enrollees and plan members in conjunction with any optional election mechanism. In the future, as technology evolves, another process may be a more appropriate minimum standard. To ensure that these points are clear, we are amending § 422.50(a)(5) to provide that beneficiaries may make elections by completing an enrollment form or by completing another CMS-approved election mechanism offered by the MA organization.

Comment: One commenter requested that CMS clarify the use of alternate election mechanisms with respect to employer or union group MA plans.

Response: Section 422.50 applies equally to all beneficiaries making MA elections and therefore applies to those individuals making an election to or from an MA plan sponsored by an employer or union as well. Current processes already established in our manual guidance for MA plans offered by employer or union groups are not changed by this revision.

Subpart B—Eligibility, Election and Enrollment

2. Eligibility to Elect a Special Needs MA Plan (§ 422.52)

Section 231 of the MMA authorized the creation of a new type of MA coordinated care plan, called a ''Specialized MA Plan for Special Needs Individuals.'' These plans will be referred to throughout as SNPs.

We believe the new requirements regarding SNPs are primarily intended to encourage more choices for certain populations by allowing organizations that specialize in the treatment of beneficiaries with particular needs to have MA contracts. These organizations could provide and coordinate services for these individuals and would be permitted to limit plan enrollment to such individuals, or to a certain proportion of such individuals. This provision could encourage organizations to develop new products in the marketplace by giving them the opportunity to develop expertise in efficiently serving special needs populations. Our overall policy goal will be to allow MA organizations as much flexibility as possible (within defined parameters), while maintaining beneficiary protections.

SNPs may restrict enrollment solely to those who are entitled to Medicaid (dually eligible), institutionalized individuals who meet the definition in § 422.2, and/or beneficiaries who have a severe or disabling condition, as defined by the Secretary in regulations. Section 231 of the MMA also gives the Secretary the authority by regulation to designate certain MA plans as SNPs if they ''disproportionately serve(s) special needs individuals.'' Special needs individuals are defined in § 422.2.

In the proposed rule, we asked for comment as to whether SNPs should be allowed to exclusively enroll certain subgroups of those categories of special needs individuals described in § 422.52(b)(1) and § 422.52(b)(2) (dual eligible or institutionalized beneficiaries) and, if so, what categories would be appropriate.

The MMA gave us the authority to waive section 1851(a)(3)(B) of the Act, which precludes beneficiaries with ESRD from enrolling in MA plans. In the proposed rule, we solicited comments as to whether we should waive this section of the Act and whether beneficiaries with ESRD should be considered to meet the requirement for special needs status.

We also have the authority to apply to SNPs a provision under section 1894(c)(4) of the Act that applies to enrollees in the Program of All-Inclusive Care for the Elderly (PACE). This section provides for deemed continued eligibility in certain situations. Specifically, it allows an beneficiary enrolled in a PACE plan who no longer meets the eligibility criteria, but who can reasonably be expected to, in the absence of continued coverage under the PACE plan, meet the criteria of the plan within a period of time not to exceed 6 months. In the proposed rule, we proposed applying this provision to individuals enrolled in SNPs who longer meet a plan's unique eligibility criteria, who can reasonably expected to meet the plans criteria within a period of time not to exceed 6 months.

In the proposed rule, we provided in § 422.52(e) that individuals who are enrolled in MA plans that are subsequently designated as SNPs would be ''grandfathered,'' that is, allowed to continue to be enrolled or choose to elect another MA plan during appropriate election periods provided to all MA eligible individuals. We proposed this based on the belief that the Congress did not intend for individuals already enrolled in an MA plan to be involuntarily disenrolled. However, we also invited comment on an alternative approach wherein any non-special needs individuals in an MA plan that is subsequently designated as an SNP would have to be involuntarily disenrolled. In this situation, we proposed to establish, through further operational guidance, an SEP for these individuals. Statutory language also provided that a newly designated MA plan may restrict future enrollment of individuals to those specialized individuals it intends to serve.

We also indicated in the proposed rule that, if we did allow ''grandfathered'' members to remain in the SNP, we would distinguish them from those individuals who join a new SNP and then lose their special needs status on other than a temporary basis. Those special needs individuals would be involuntarily disenrolled after losing their special needs status (and after any period of deemed continued eligibility, if appropriate) and receiving proper notice. SNPs that exclusively enroll special needs individuals would be required to inform individuals before their initial enrollment that they could only remain enrolled in the plan for as long as they were considered special needs individuals as defined by CMS.

Comment: One commenter felt that CMS should not allow SNPs to exclusively enroll certain subgroups of dual eligible or institutionalized beneficiaries. The commenter's rationale was that requiring MA organizations to accept all dual eligibles into its specialized MA plan would maintain the integrity of the dual-eligible risk pool and prevent the offering of an SNP plan to those who are the least poor (and presumably, most healthy) segment of duals. On the other hand, several commenters suggested that CMS allow SNPs that would enroll subgroups of dual eligibles if supported by a State Medicaid agency. The vast majority of commenters supported allowing SNPs to serve subsets of both the dual eligible and institutionalized populations.

The most prevalent rationale for allowing subsets of dual eligibles was to allow States to develop specialized Medicaid programs to compliment Medicare coverage by SNPs. Most commenters described the difficulties and complexities of serving all dual eligibles as impediments and disincentives to developing a program to coordinate Medicaid managed care programs with Medicare. If required to serve all dual eligible beneficiaries, MA organizations would have to offer

Medicaid-covered benefits, such as long-term care, to individuals who are not eligible for full Medicaid benefits. One commenter stated that allowing subsets of dual eligibles would also facilitate transitioning full dual eligibles from Medicaid prescription coverage to Medicare Part D coverage in 2006. Another commenter suggested that CMS clarify that plans must uniformly offer the same set of benefits to all classes of dual eligibles as provided under the State's Medicaid program. Several commenters recommended that CMS let the MA organization propose eligibility criteria and then evaluate its plan, delivery systems, and related programs, possibly modifying them as part of the review and approval process. Some commenters noted the significant investment of time and resources required to develop targeted clinical programs for different subgroups with different, complex conditions.

Commenters also suggested allowing specific subsets, including full benefit dual eligibles, the frail elderly, those who are nursing home certifiable, children or adults with physical disabilities, developmental disabilities or mental impairments, and community-based or institutional individuals.

Two commenters recommended that CMS not include subsets of duals in the third category of specialized MA plan eligibles, those with severe or disabling conditions. The rationale given was that the identifying characteristics of subsets of duals are not appropriately described within the third category and these individuals should remain in the second category.

Once commenter recommended allowing organizations to serve other subgroups of Medicaid eligible and institutionalized if there is a pervasive justification based on common characteristics of the subgroup, that is, institutionalized beneficiaries in a specified network of nursing homes.

Several commenters stated that adverse selection would be mitigated by phase-in of risk adjustment because payment would take into consideration the individual's disease category.

Response: Consistent with the majority of these comments, we do not intend to adopt a regulation that would preclude MA organizations from offering SNPs to appropriate subsets of the population in a plan service area, including subsets within the SNP populations identified in the statute. Thus, in the interest of facilitating the coordinated delivery of Medicare and Medicaid services, we will consider requests for SNPs that serve certain subsets of dual eligibles and institutionalized individuals on a case-by-case basis. Subsets of those two categories will be included in category one and category two respectively, rather than in the third category of special needs individuals, those with chronic or disabling conditions. In addition, because of the unique nature of some plans serving the institutionalized and dual eligibles, we will also consider subsets based on common characteristics, such as a specific network of facilities and Medicaid eligibility. We will provide further operational guidance following publication of this rule.

Comment: The MMA allows for the enrollment of ESRD beneficiaries in SNPs designed for this population. One commenter said that CMS should delay enrollment of ESRD beneficiaries in MA plans until results of CMS' capitated ESRD Disease Management demonstration are available. The commenter also objected to allowing ESRD patients to enroll in managed care because, in the commenter's view, managed care plans disrupt existing relationships between patients and health care providers. The commenter expressed concerns that an ESRD patient who drops or declines Medigap insurance to join a managed care plan would permanently be locked into the managed care plan and could not switch to Original Medicare, since ESRD would make him/her ineligible for Medigap coverage. The remainder of those commenting on permitting ESRD SNPs supported the proposal.

Response: Individuals with ESRD may choose to receive care under an MA plan for a variety of reasons, including coordination of care and lower out-of-pocket costs. Anecdotal experience with the MA program has shown that MA enrollees with ESRD generally remain enrolled in their plan, or join another existing plan if the one in which they are enrolled terminates. We believe that these beneficiaries should have the option of enrolling in an MA plan, if they so desire. Therefore, we will amend § 422.50(a)(2) by adding language to allow SNPs to serve ESRD individuals.

In order to mitigate the commenter's concerns, we would require that, prior to enrollment in an MA SNP, the organization notify potential enrollees that enrollment is fully optional and of the potential impact that their enrollment could have on their Medigap rights. In addition, MA Organizations will be required to provide clear and accurate provider information for potential enrollees so they may determine whether their current providers are part of the specialized MA plan's network.

Comment: Many commenters supported the proposed approach at § 422.52(e) to allow individuals already enrolled in an MA plan that we subsequently designate as an SNP to remain enrolled or be allowed to elect another other MA plan. Most of these commenters also recommended that CMS allow for a Special Election Period (SEP) to facilitate selecting a new MA plan or Original Medicare. Several commenters remarked on the need to maintain adequate enrollment levels once an SNP gains a new designation. None of the commenters supported the alternative proposal under which non-special needs individuals would have to be involuntarily disenrolled if their MA plan became an SNP.

Response: We will allow members of MA plans that are subsequently ''redesignated'' as SNPs to be ''grandfathered,'' that is, remain enrolled in that plan indefinitely. These individuals may not be involuntarily disenrolled on the basis of not meeting the definition of special needs individual. However, once a grandfathered individual voluntarily disenrolls from the SNP, he or she would not be eligible to reenroll in that SNP unless he or she meets the definition of special need individual. We will establish an SEP for these individuals for exceptional circumstances in further operational guidance. An SNP that chooses to exclusively enroll special needs individuals will not be considered a ''disproportionate share'' SNP, as defined in § 422.2, on the basis of serving ''grandfathered'' members.

Comment: Many commenters supported not requiring plans to involuntarily disenroll beneficiaries who lose their special needs plan eligibility if it is reasonable to assume that they would again meet the special needs eligibility criteria within a certain period as determined by CMS. Some commenters stated that it is not uncommon for beneficiaries to have temporary lapses in eligibility, particularly in situations where a dual eligible loses Medicaid eligibility due to a temporary change in financial circumstances or failure to provide information for recertification. The commenters generally believed that continued eligibility leads to continuity of care and improved clinical outcomes. Two commenters requested an additional 6-month ''grace period'' (commenter's terminology) for individuals who lose their eligibility as well as retroactive payments for their care in the event that eligibility is established retroactively.

One commenter recommended that CMS continue funding Part D and other benefits for the entire ''30-day notice period'' (commenter's terminology) regardless of an individual's eligibility to enroll in a SNP.

One commenter requested continued eligibility for ''exclusive'' as well as ''non-exclusive'' plans (commenter's terminology), including MA plans that may temporarily fall below the required threshold for the special needs designation.

Response: We believe that the Congress' goal was to encourage continuity of care for these at-risk individuals and that a period of deemed continued eligibility for a minimum of 30 days but no longer than 6 months is reasonable for beneficiaries who are likely to regain eligibility. The 6-month period is consistent with the PACE language at § 460.160, which provides that a participant may be deemed to continue to be eligible if, in the absence of continued coverage, the participant reasonably would be expected to meet the requirement within the next 6 months. However, we will not include ''in the absence of continued coverage'' in § 422.52(d).

Our rationale is that this appears to reference ineligibility due to a health condition that could deteriorate without plan membership. In the case of an SNP for dual eligibles, a lapse in SNP eligibility could be due to a lapse of Medicaid eligibility, and such eligibility may be based on the beneficiary's financial circumstances, not his or her health condition.

The MA organization may choose any length of time from 30 days through 6 months for deemed continued eligibility as long as it applies this period consistently among all members in its plan and fully informs its members of this time period. Further guidance on applying deemed eligibility will be provided in operational instructions following publication of this regulation.

We believe that the ''30-day notice period'' referred to by one commenter is from our interim guidance for SNPs, issued as part of its 2005 Call Letter. This guidance established a 30-day minimum timeframe for continued eligibility for an SNP enrollee who loses his or her special needs status. This individual is a member during the period of deemed continued eligibility and until his or her disenrollment becomes effective. Payments will continue on the enrollee's behalf until the period of deemed continued eligibility ends and the enrollee is involuntarily disenrolled. Retroactive payment will not be necessary in these instances.

All SNPs, including ''disproportionate percentage'' SNPs, as defined in § 422.2, may apply the deemed eligibility provision. Deemed eligibles would be counted toward the number of special needs individuals enrolled in the SNP rather than toward the number of non-special needs individuals.

Comment: Several commenters supported allowing SNPs to disenroll enrollees who no longer meet the special needs eligibility criteria. Two commenters wanted SNPs to have the choice of whether to continue to provide Medicare services to individuals who lose special needs status. Another commenter supported involuntary disenrollment for exclusive MA SNPs only, stating that this requirement would hinder disproportionate SNPs' ability to maintain enrollment at or above the regulatory threshold.

Response: In our interim guidance and our proposed rule, we interpreted the statutory phrase ''exclusively serves special needs individuals'' to mean that the plan is exclusively marketed to special needs individuals and exclusively enrolls special needs individuals. This interpretation allowed us to permit existing non-special needs enrollees to remain enrolled in an MA plan that changed its status to an SNP.

Thus, under this definition, existing enrollees who did not enroll when the plan was an SNP would not be affected by the plan definition, and we do not believe they should be disenrolled. Moreover, the existence of such enrollees does not preclude the plan from remaining a plan that ''exclusively serves≥(that is, markets to and enrolls) special needs individuals. As noted above, however, an individual who enrolls in an SNP as a special needs enrollee is different, since he or she would have no expectation of being enrolled in that plan if he or she were not in the special needs category. The case of an SNP that has never had non-SNP enrollees is also different, as any enrollee that it markets to or enrolls would have to be a special needs enrollee, if it is an ''exclusive'' plan.

In order to address these latter situations, we will add a new part (iv) to § 422.74(b)(2) to show that in these cases loss of special needs status (and of deemed continued eligibility, if applicable) is a basis for required disenrollment from an SNP that enrolls only special needs individuals.

We have the authority to waive minimum enrollment requirements as necessary. Therefore, we do not envision the minimum enrollment requirements adversely affecting disproportionate share SNPs.

Comment: One commenter recommended that CMS allow MA SNPs to charge an enrollee for benefits no longer covered by the State or Federal cost-sharing arrangements and to terminate coverage for nonpayment of premiums or cost sharing.

Response: An SNP is the same as any other MA plan with respect to rules governing the charges that may be imposed on enrollees. Enrollees may be charged for benefits that would not otherwise be covered by Medicare. Under § 422.74(d)(1), coverage may be terminated for a failure to pay premiums. As discussed below in connection with disenrollment for disruptive behavior, a failure to pay cost sharing is not in itself a basis for disenrollment.

Comment: Two commenters asked for clarification of whether the regulation refers to Special Needs Health Plans or the Special Needs Health Options.

Response: The regulation refers to a ''Specialized MA plan for special needs individuals'' (SNPs), as created by Section 231 of the MMA.

3. Continuation of Enrollment for MA Local Plans (§ 422.54)

The MMA limits the offering of MA plan continuation areas to MA local plans only and we made this conforming change at § 422.54. We received no comments on this section and adopted the conforming changes as proposed.

4. Enrollment in an MA MSA Plan (§ 422.56)

Section 233 amended the Act to eliminate the cap on the number of individuals that may enroll in MA MSA plans removed the existing deadline for enrolling in such a plan. Because this deadline had already passed without anyone enrolling in an MSA plan, the original MSA plan provisions had become a nullity. The effect of section 233 was to make the authority to offer MSA plans permanent and unlimited. This change is reflected at § 422.56, along with new language allowing the Secretary to permit enrollment in MSAs by enrollees of other Federal. We included this language to reflect the fact that, under the statute, such enrollment could be authorized contingent on the adoption of new policies by the OPM.

Comment: Two commenters suggested deleting the language authorizing the Secretary to permit enrollment in MSAs by enrollees of the Federal programs specified. Both commenters contended that it was unlikely that OPM would ever be able to certify that MSA enrollment would not raise costs in the FEHB, Veterans' Administration, or

TRICARE programs and that, accordingly, the inclusion of this language is unnecessary.

Response: The statute at section 1851(b)(2) provides for the potential for such individuals to become eligible to enroll in an MSA plan. Therefore, our clarification of § 422.56(b) supporting this provision is appropriate.

5. Election Process (§ 422.60)

In proposed § 422.60, we set forth changes that would allow other election and notice mechanisms other than paper forms or written documents. We also clarified that MA organizations may submit requests to restrict enrollment for capacity reasons to CMS at any time during the year.

Comment: Two commenters supported the conforming revisions to § 422.60 permitting us to approve alternate election mechanisms, as discussed in the comments on proposed § 422.50(a)(5). The commenters also approved of the clarification to § 422.60(b) regarding requests for enrollment limits due to capacity reasons.

Response: We adopt these revisions as proposed.

Comment: One commenter suggested that CMS make further amendments to the regulatory text to ensure that the current options we have established for individuals to elect MA plans sponsored by employer or union groups are retained, including the policy that documentation may be retained by an employer or union group rather than the MA plan.

Response: As discussed above, we are confident that the proposed revisions provide us with sufficient flexibility to foster innovative election processes that use modern technology for all individuals, not just employer or union groups. Therefore, it is not necessary to reiterate that these alternative enrollment mechanisms are also available to employers or union groups. We will continue to retain current policy for employer or union group elections in our operational guidance and as an option for MA organizations.

Comment: One commenter suggested that CMS require MA and MA-PD plans to accept AI/AN enrollees even if a plan has received CMS approval to close enrollment for capacity reasons.

Response: The ability to request a capacity limit is an important element of the MA program that helps ensure that plan enrollees will have sufficient access to needed providers and services. CMS' approval of a capacity limit request indicates that we agree with the requesting MA organization that its defined network of providers is sufficient to deliver health care only to a limited number of plan members. Thus, we do not permit the MA organization to enroll any individual beyond the capacity limit of a given plan, and we do not believe it would be appropriate to undermine this protection by waiving capacity limits for the AI/AN population or any other group.

Comment: Two commenters requested that CMS modify the regulations to more clearly allow for what the commenter referred to as ''passive elections.''

Response: The elections to which the commenters are referring are those in which an individual is informed that the process for making an election of a particular plan is taking no action, while other options are exercised by declaring an affirmative intent to elect that option. CMS have limited such a process to situations when it can be reasonably concluded that an individual will clearly want to enroll in the MA plan offered by the same organization.

We do not believe that a regulatory change is needed to continue to allow such elections. The revisions made to § 422.50(a)(5) and the conforming revisions to § 422.60 provide us with appropriate flexibility to define and approve MA election mechanisms, including allowing such ''passive elections'' as described above in specific limited circumstances.

6. Election of Coverage Under an MA Plan (§ 422.62)

Similar to the election periods in place in past years, the MA *Annual Coordinated Election Period* will run from November 15 through December 31 of each year. For 2006, the annual coordinated election period is extended through May 15, 2006.

Based on our interpretation of the MMA, we proposed revising § 422.62 to ensure that an individual who is newly eligible for MA has the full opportunity to elect an MA plan as part of their *Initial Coverage Election Period*. In developing the proposed rule, we determined that the intent of the Congress was to provide for an initial coverage election period for MA that ends on the later of the day it would end under pre-MMA rules or the last day of the Medicare Part B initial enrollment period. This approach extends an individual's MA initial election period in some instances, and never reduces or eliminates it.

Through 2005, the *Open Enrollment Period* extends throughout the year, providing unlimited opportunities for MA eligible beneficiaries to enroll in, disenroll from, and or change enrollment in an MA plan. This change was reflected in § 422.62(a)(3) of our proposed regulations.

Section 1851(e)(2)(B)(1) of the Act was revised to establish that the open enrollment period in 2006 will be the first 6 months of the year. In addition, individuals who are newly eligible for MA in 2006 are provided an open enrollment period that consists of the first 6 months the individual is MA eligible, but cannot extend past December 31, 2006.

Under revised section 1851(e)(2)(C)(i) of the Act, the open enrollment period for 2007 and subsequent years will be the first 3 months of each year. In addition, individuals who first become MA eligible during 2007 and subsequent years will be provided an open enrollment period that consists of the first 3 months the individual is MA eligible, not to extend past December 31, 2006. Although this specific period does not extend past December 31, 2006, it is important to remember that all individuals will be provided a 3-month open enrollment period from January through March 2007, as discussed in this section.

Section 1851(e)(2)(C) of the Act limits a change of election made during an open enrollment period in 2006 and later years to the same type of plan in which the individual making the election is already enrolled. Specifically, an individual in an MA plan that does not provide drug coverage may change only to another similar MA plan, or to original Medicare, but may not enroll in an MA plan that provides Part D coverage, or enroll in a Part D plan. Similarly, an individual enrolled in an MA plan that includes Part D coverage may enroll only in another MA plan with Part D coverage, or change to original Medicare coverage with an election of a Part D plan. As noted in the proposed rule, we clarified a conflict between clause I and II of section 1851(e)(2)(C)(iii) of the Act. Clause (I) of section 1851(e)(2)(C)(iii) states that an individual who is ''enrolled in an MA plan that does provide qualified prescription drug coverage,'' may only elect a plan that does not provide that coverage. A literal reading of this language would be in direct conflict with clause (II) of that same section, which says that an individual who is enrolled in an MA plan that provides qualified prescription drug coverage may not enroll in an MA plan that provides no Part D coverage.

This contradiction, plus (1) the fact that section 1851(e)(2)(C)(iii)(I) of the Act refers to a ''another'' MA plan that ''does not'' provide Part D coverage, (2) the fact that clause (I) is contrasted with

clause (II) with the word ''or'', and (3) committee report language, make it clear that the word ''not'' was inadvertently omitted from the first clause of section 1851(e)(2)(C)(iii) of the Act.

Comment: Numerous commenters opposed the ''lock-in'', that is, the statutory provisions that limit beneficiaries from choosing a different type of coverage to certain times of the year. Several commenters stated that these provisions severely limit the choice of beneficiaries. Others commented that implementing lock-in under the MA program at the initiation of the new Part D program would be confusing to beneficiaries. Commenters also noted that such a provision would have a negative impact on the MA organizations, by making it difficult to maintain a dedicated sales staff and increasing the administrative costs and burden of educating beneficiaries about both Part D and MA changes.

Response: The provisions that limit the times in which an individual may change his or her election were originally created by the BBA, and were to become effective during 2002. However, because of subsequent statutory changes, these provisions have never taken full effect (except for a temporary period during 2002). These provisions were modified by the MMA to incorporate the Part D prescription drug benefit and the statute is clear on their applicability. Thus, we have no authority to modify these requirements.

Comment: One commenter suggested that CMS develop appropriate procedures to administer these election restrictions and inform organizations as to what type of plan an individual is eligible to elect (for example, an MA only or an MA-PD plan). Another commenter recommended that the organization have access to information about whether an individual is eligible to elect a certain plan, both in advance of an enrollment application and upon receipt of an enrollment application.

Response: We understand that we will need to maintain data history of the number of times an individual has made an election during a specific election period, as well as the type of plan an individual is eligible to elect. Such information will be necessary in order to determine whether an individual is eligible to elect an MA plan at a given time. We will work with plans to establish a reliable process to determine the eligibility of an individual based on these requirements.

Comment: Several commenters responded to the request for comments on the provision that an enrollee may only change to the same type of plan (either with drug coverage or without) during the open enrollment period. Some commenters opposed the interpretation that restricts a beneficiary from switching plans, even when life circumstances had changed. Others supported the interpretation and indicated that such a provision reinforced the overall integrity of the program. Others believe that we need to maintain flexibility with employer-sponsored plans.

Response: After review of the statutory provisions and the comments, we believe that the Congress clearly intended that a beneficiary may obtain or discontinue Part D coverage *ONLY* during the annual coordinated election period that begins in November each year. Notwithstanding SEPs established by the statute and in our regulations and subsequent guidance, it is only during the Annual Coordinated Election Period that all Medicare beneficiaries are free to elect among all available options, whether original Medicare, MA plans, MA-PD plans or PDPs. The statutory provisions governing Part D in 1860D–1 do not provide for an open enrollment period that would allow beneficiaries to elect the prescription drug benefit outside of the AEP. Permitting beneficiaries to discontinue Part D coverage at any time during the year, without a corresponding election period to enroll in such coverage, could result in a gap in coverage that may result in a late enrollment penalty. Therefore, we believe that it is appropriate to interpret the statute to require that individuals may not make an election that would result in adding or dropping prescription drug coverage except during the annual election period.

Comment: One commenter recommended that CMS clarify how the annual coordinated election period and the open enrollment period will be administered in 2006, since these periods overlap from January 2006 through May 15, 2006.

Response: In 2006, we envision that the annual coordinated election period will provide each individual with the ability to choose either an MA plan or original Medicare, with or without drug coverage. The open enrollment period will provide individuals the opportunity to change their election from the MA program to original Medicare (or vice versa), but not to obtain or discontinue drug coverage. We will provide information about these election periods in beneficiary materials, such as the Medicare & You Handbook.

Comment: A few commenters submitted comments regarding the special election periods (SEPs), as described at § 422.62(b). One commenter asked if CMS expected to apply the SEPs established under the M+C program to the MA program. Another commenter requested confirmation that the current SEP for PACE enrollees (described in manual guidance) would be applied to the MA program. One commenter suggested that CMS consider an exception to the Open Enrollment Period for SNPs and for individuals eligible for both Medicare and Medicaid.

In addition, a commenter asked CMS to consider the creation of an SEP for beneficiaries in markets with MA market penetration rates below 20 percent; such an SEP would allow time for educating beneficiaries on MA plans and how they operate. Many commenters submitted comments on establishing SEPs for special needs plans. The commenters generally approved of a permissive special election period policy to allow special needs individuals to change plans at any time. Others believe that the enrollment periods established in § 422.62 do not provide sufficient opportunity for beneficiaries to enroll in a special needs plan.

Response: We have historically included in our regulations those SEPs that have been specifically named in the statute, and established SEPs for exceptional circumstances in our operational guidance. We will review the SEPs in current MA guidance and consider their applicability for the MA program in 2006, as well as consider new SEPs that may be necessary to coordinate the new Part D program. We appreciate the suggestions provided by the commenters and will consider these in developing guidance following publication of the rule.

Comment: Several commenters addressed the AI/AN population and the need to modify the regulations to allow AI/AN individuals to switch between MA or MA-PD at various times rather than be limited to changing only at certain times during the year.

Response: We recognize the need to coordinate between the IHS, Tribe, or Tribal organization, or Urban Indian (I/T/U) programs. We have the authority to recognize certain circumstances as exceptional and provide special election periods. Providing such exceptions, however, would not always benefit an individual, as we discussed in our response to a previous comment under § 422.50 regarding capacity limits. Such limits are necessary to ensure that health plans have the appropriate number of providers and are able to provide access to all beneficiaries enrolled in their plan. As discussed in the previous comment regarding

establishment of SEPs in operational guidance, we are not establishing any non-statutory SEPs in the regulation, but retain the authority to establish an SEP in the future under exceptional conditions. This same policy applies to the AI/AN population.

7. Coordination of Enrollment and Disenrollment through MA Organizations (§ 422.66)

In keeping with our proposed clarification at § 422.50(a)(5) regarding election mechanisms other than, and in addition to, paper forms, we proposed conforming changes at § 422.66. We also proposed similar changes in § 422.66(b) to provide for a more efficient notice process, including eliminating the requirement for MA plans to send a copy of the individual's disenrollment request back to the individual.

Section 1860D–21(b) provides the Secretary with the authority to implement default enrollment rules at 1851(c)(3)(A)(ii) for the MA-PD program, which begins in 2006. This provision permits the establishment of procedures whereby an individual currently enrolled in a health plan offered by an MA organization at the time of his or her Initial Coverage Election Period is deemed to have elected an MA-PD plan offered by the organization if he or she does not elect to receive coverage other than through that organization. In our proposed rule, we discussed the requirement for individuals to make affirmative elections upon becoming entitled to Medicare as provided under § 422.66. Affirmative elections may ensure that individuals have the ability to remain with the organization that offers their health plan and protects beneficiary choice by requiring an individual to make an affirmative election. However, based upon comments received, we will revise the regulatory language to retain the ability to allow for default enrollment, as discussed in our responses below.

At § 422.66(e) we also proposed to add language that implemented new rules for continuing MA coverage for individuals enrolled in MA plans as of December 31, 2005. Under section 1860D–21(b)(2), individuals enrolled in an MA plan that, as of December 31, 2005, provides any prescription drug coverage would be deemed to be enrolled in an MA-PD plan offered by that same organization as of January 1, 2006. If an individual is enrolled with an MA organization that offers more than one MA plan that includes drug coverage, and is enrolled in one of those plans as of December 31, 2005, the individual would be deemed to have elected to remain enrolled in that plan on January 1, 2006 if it becomes an MA-PD plan on that date. An individual enrolled in an MA-PD plan on December 31 of a year would be deemed to elect to remain enrolled in that plan on January 1 of the following year (that is, the next day).

Comment: Several comments were received regarding the revisions to the disenrollment process described above. Several commenters supported the change in language allowing optional mechanisms for disenrollment elections. Several commenters also supported the elimination of the requirement that organizations return a copy of the disenrollment request to the individual.

Response: We received no opposing comments to these provisions and adopt these provisions as proposed.

Comment: One commenter recommended that CMS clarify that MA plan members who have selected prescription drug coverage as an optional supplemental benefit, and are receiving such benefits as of December 31, 2005, will be deemed to have enrolled in an MA-PD plan.

Response: Individuals who are enrolled in an MA that offers any prescription drug coverage, including coverage offered as an optional supplemental benefit, as of December 31, 2005, will be deemed to have enrolled into an MA-PD plan offered by that organization.

Comment: Several commenters stated that additional information is needed to implement the deemed enrollment provision for MA enrollees who do not make an affirmative election into an MA-PD plan. If the MA organization offers more than one MA-PD plan, it is unclear into which plan the individual will be deemed enrolled.

Response: We will provide further guidance to MA organizations on this issue, as we do at the end of each contract year through our plan ''cross-walk'' guidance. Under this guidance, the existing policy, under which the MA organization may designate the plan that is ''continuing'' into the next year, would apply to this situation.

Comment: Several commenters supported and opposed the implementation of default enrollment rules as discussed at section 1851(c)(3)(A)(ii) of the Act for the MA-PD program.

Several commenters support implementing the default enrollment provision and believe that it would simplify the enrollment process for beneficiaries. They believe that such a process could be coupled with advanced notice that would also give the member the opportunity to ''opt-out'' of the ''default'' enrollment. Other commenters stated that the MA organization should have the option of applying ''default'' enrollment in certain situations, for example, with its employer group members. Commenters stated that if the MA organization chose to implement the option, each beneficiary would also be provided the option to decline prior to enrollment.

Several commenters opposed default enrollment and supported requiring an affirmative election by the beneficiary. These commenters believe that a default enrollment process would be difficult and confusing for beneficiaries. They do not believe that beneficiaries should be ''defaulted'' into the same health plan that provided pre-Medicare coverage. Many commenters recommended that MA plans obtain accurate information from prospective enrollees through the affirmative election process, and, without such a process, MA plans may not have up-to-date information about the beneficiary. Finally, there are those who neither support nor oppose the default enrollment process, but instead suggest that we modify the regulatory language to allow us to implement such a provision in the future.

Response: The commenters raise several good points regarding the implications of default enrollment. The intent of default enrollment is not to reduce beneficiary choice, but rather to ensure continuity of care. At this time, we will retain the flexibility to implement this provision through future instructions and guidance to MA organizations. We do not envision mandating that organizations use default procedures, but instead would give organizations the option of implementing such a process for its enrollees. Any such process would require that advance notice be provided to an individual, and that affected individuals have the ability to ''opt out'' of such an enrollment. We believe that we can achieve the same flexibility provided with respect to default enrollment that exists at § 422.60(b)(3)(c), which allows for elections using alternative mechanisms. Thus, we have revised proposed § 422.66(d)(5) to allow us to offer default enrollment as an option in the future, in a form and manner specified by CMS.

Comment: One commenter suggested that, rather than prohibit default enrollment, CMS should develop a method to allow enrollees in an MA plan with or without prescription drug coverage, who do not make an election by December 31, 2005 to remain with their current MA organization in an MA-PD plan. Another commenter assumed that CMS intends that

individuals enrolled in an MA plan without drugs who do not make a plan election into an MA-PD plan for January 1, 2006 will be defaulted into original Medicare.

Response: The statute provides for an individual in an MA plan with drug coverage on December 31, 2005, to be deemed enrolled in an MA-PD plan as of January 1, 2006. However, the statute does not allow an individual who is in an MA-only plan that continues in January 2006 to be deemed to make an MA-PD election. The statute is clear that those individuals will remain in an MA-only plan unless those individuals take an action to elect an MA-PD plan. Pursuant to section 1861(b)(3) of the Act, individuals may be deemed to have elected Original Medicare only if the MA-only plan in which they are enrolled is terminated. Thus, in general, we would not be defaulting MA plan members into original Medicare.

Comment: Several commenters recommended that CMS coordinate the enrollment of full benefit dual eligible individuals. A few commenters suggested that CMS apply the default enrollment provisions for dual eligible individuals who have not otherwise elected an MA-PD or PDP into an MA-PD that is administered by an MA organization that operates the Medicaid managed care organization in which the individual is enrolled. Another commenter supports the inclusion of sufficient flexibility in our regulations to enable us to develop solutions that best meet the needs of beneficiaries and are coordinated with the MA organizations.

Response: As discussed above, we will consider requests to adopt such default enrollment processes only with respect to a newly-Medicare eligible individual who is enrolled with an organization as a Medicaid enrollee at the time he or she becomes eligible for Medicare. In such a case, the individual could be considered by default to have elected that organization for purposes of Medicare benefits upon the individual's becoming eligible for Medicare. The default authority in 1851(c)(3)(A)(ii) of the Act would not, however, permit an individual to be considered by default to have elected an MA-PD plan if he or she was already a Medicare beneficiary and had elected not to receive Medicare benefits through an MA organization. Therefore, we decline to enroll by default existing full-benefit dual eligible individuals into an MA-PD if they are currently in Original Medicare and only receive Medicaid benefits through that organization. We will continue to evaluate alternatives to facilitate enrollment in Part D for this population.

Comment: Several commenters suggest that each MA plan that becomes an MA-PD plan send a notice to their enrollees that the enrollees will be automatically enrolled in the MA-PD plan unless they choose to change plans. Further, it is suggested that CMS create a model letter for this purpose.

Response: MA plans are required to send out notices in October of every year to their members, also known as the annual notice of change (ANOC). We will revise the language in the ANOC for MA plans to provide to members in October 2005 in order to reflect this policy.

Comment: Several commenters recommend that CMS establish a default enrollment process for AI/AN if a certain plan meets AI/AN needs.

Response: CMS recognizes the need to coordinate between the I/T/U programs. Given the new regulatory language at § 422.66(d)(5), which allows us to offer default enrollment as an option to MA organizations, we could consider requests by MA organizations to offer default enrollment to the AI/AN population in the case of newly-Medicare eligible individuals who are enrolled in a non-Medicare product of an MA organization at the time they become Medicare eligible.

8. Effective Dates of Coverage and Change of Coverage (§ 422.68)

To coordinate the effective date of elections with the 2006 special annual coordinated election period (to be held November 15, 2005 through May 15, 2006), section 1851(f)(3) of the Act was amended by the MMA to provide that the effective date of elections for the annual coordinated election period does not apply during the 2006 special annual election period, when enrollment will be effective on the first day of the month following the month in which an election is made. We proposed to revise § 422.68(b) to provide for this coordination and to make the effective date of elections in the annual coordinated election period for 2006 that are made in 2006 (that is, from January 1 through May 15, 2006) the first day of the calendar month following the month in which the election is made. We received no comments on this section and adopted the proposed language as final.

9. Disenrollment by the MA Organization (§ 422.74)

Under the current regulations at § 422.74(d)(1), MA plans are required to provide, at a minimum, a 90-day grace period before disenrolling individuals for failure to pay plan premiums. Thus, MA plans must maintain enrollment for individuals who do not pay their premiums for more than 90 days.

We proposed to provide greater flexibility to MA organizations by replacing the 90-day grace period in § 422.74(d)(1) with the long-standing approach under § 417.460(c)(1), which governs disenrollment from HMOs with cost contracts under section 1876. Under this proposal, we would instead specify that a disenrollment could be effectuated no sooner than 1 month from the date the premium was due.

We have also proposed revisions to the regulations at § 422.74(d)(2) regarding disenrollment of an individual for disruptive behavior. Our goal was to create a more objective definition that is based upon an individual's behavior, rather than upon the application of such subjective terms as ''unruly,'' ''abusive,'' and ''uncooperative.'' We also recognized that, in revising this definition, we needed to strike a balance that would ensure all individuals are afforded protection from unwarranted disenrollment actions while protecting the health and safety of all those concerned including the individual. The best solution is to create a definition of disruptive behavior based on objective criteria, ensure that MA organizations make serious efforts to resolve problems with beneficiaries who are disruptive, and to require MA organizations to make ''reasonable accommodations'' for vulnerable beneficiaries, including those with serious mental illness. Furthermore, we will ensure that CMS staff with appropriate clinical or medical expertise will be involved in the review of the MA organization's request before we make a final decision. We will work with organizations that ask to disenroll these individuals on a case-by-case basis to ensure that they are not left without Part D coverage. We will also remove the provision for an expedited disenrollment we had proposed and ensure that MA organizations provide due process before disenrolling an individual.

Comment: Several commenters supported the proposed revisions to § 422.74(d)(1) regarding procedures for involuntary disenrollment for failure to pay plan premiums. Other commenters opposed these revisions as ''overly broad'' and felt the lack of a specific time frame could be a disadvantage for plan enrollees.

Response: Our proposed changes to this section were intended to provide flexibility for MA organizations in addressing the issue of plan members who fail to pay required plan premiums. Under the existing rule, MA organizations were obligated to provide

all plan benefits to an individual who has failed to pay required plan premiums for a full 90-day period. This period often exceeded 90 days because the notice requirements we imposed fell after the end of the 90-day period, but must still be met by the organization before the individual could be disenrolled. Our experience and feedback from MA organizations indicated that these requirements, while intended to protect beneficiaries enrolled in MA plans, may instead artificially inflate plan premiums because MA organizations are required to continue to provide services to these beneficiaries for up to 4 months, even though they have not paid the required plan premiums.

After reviewing the comments and feedback we received on the proposed rule, we determined that it would be prudent to include a minimum grace period in the revisions we are making to address this issue. Therefore, we have revised this section to include a 1-month grace period during which an enrollee who has failed to pay required premiums must be notified of the impending disenrollment action and afforded the opportunity to pay past due premiums in full or under payment terms agreed upon by the beneficiary and the MA organization, as the organization allows. This period will begin on the first day of the month for which the premium was unpaid. For example, the grace period for a March premium will begin March 1st and, if the organization does not receive payment by March 31st, the individual will be disenrolled effective April 1st. We will provide specific time frames for required notices in additional guidance to ensure beneficiaries have adequate time to respond before disenrollment takes effect. Since we are establishing this 1-month grace period as a minimum requirement, MA organizations still have the option of lengthening this period.

Comment: Three commenters suggested that CMS allow MA organizations to ''move'' or ''default'' plan members who have failed to pay premiums in one MA plan to another MA plan in the same organization that is offered at a lower or no premium, so that beneficiaries do not suffer an interruption in MA benefits.

Response: This suggestion is inconsistent with the statute. Section 1851(g)(3)(C)(i) of the Act clearly provides that individuals who are disenrolled from an MA plan for failing to pay premiums are deemed to have elected original Medicare.

Comment: Several commenters submitted comments on the proposed revisions to § 422.74(d)(2) concerning the disenrollment of individuals who exhibit disruptive behavior. Some commenters supported the proposed approach, noting that the inability to effectuate such disenrollment has been an ongoing issue for MA plans. Other commenters recommended that CMS further clarify the meaning of the term ''decision-making capacity,'' and one commenter in particular suggested that CMS adopt a definition based on legal conservatorship.

Several commenters, on the other hand, expressed concern that the expanded definition of disruptive behavior does not adequately protect individuals whose behavior is induced by a mental illness, a medical condition, or certain prescribed drugs. These commenters were concerned about the loss of protection for individuals with diminished mental capacity. Several commenters expressed concern that the definition of disruptive behavior was overly subjective, particularly the use of terms such as ''unruly'', ''abusive'' and ''uncooperative.''

Response: In the final rule, we aim to strike a balance between allowing MA organizations to disenroll individuals who exhibit disruptive behavior and creating adequate protections for individuals who face involuntary disenrollment from a plan. Since the statute (at section 1851(g)(3)(B)(ii) of the Act) permits an MA organization to disenroll an individual who engages in disruptive behavior, we must establish a process for allowing these types of disenrollments. At the same time, we recognize that such a process must include adequate safeguards for individuals whose disruptive behavior is due to mental illness or a medical condition, especially in light of the crucial importance of prescription drug therapy for these individuals. It is also important to recognize that some prescription drug therapies may well induce such behavior.

Therefore, we are revising our proposed definition of disruptive behavior in § 422.74(d)(2)(i) of the final rule to focus on the behavior that substantially impairs the plan's ability to arrange or provide care for the individual or other plan members. We recognized that terms such as ''unruly'', ''abusive'', ''uncooperative'', as well as an assessment of the enrollee's ''decision-making capacity'' are subjective terms that make reviewing and approving such requests difficult.

In addition, we agree with commenters that arranging or providing care for individuals with mental illness, cognitive impairments such as Alzheimer's disease or other dementias, and medical conditions and treatments that may cause disruptive behavior warrants special consideration. Therefore, we are revising § 422.74(d)(2)(v) to also require MA organizations to provide a ''reasonable accommodation'' to individuals in such exceptional circumstances that we deem necessary. Such accommodations could include providing the individual with a SEP to choose another plan, or requiring the plan to maintain the individual's enrollment until the end of the year, when the individual could choose another plan. We will determine the type of accommodation necessary after a case-by-case review of the needs of all parties involved. This review will be conducted as part of CMS' existing review and approval process required under § 422.74(d)(2)(v). The regulations (at § 422.74(d)(2)(iii)), will continue to require that that before an organization can request to disenroll a member for disruptive behavior, it first must make a serious effort to resolve the problems presented by the individual's behavior, including the use of the organization's grievance procedures. The MA organization must then document the individual's behavior, its own efforts to resolve the problem, and the use or attempted use of its internal grievance procedures.

We believe that these policies will achieve the twin goals of permitting involuntary disenrollment when appropriate due to an individual's disruptive behavior, while also establishing necessary protections for beneficiaries in certain circumstances.

Comment: One commenter stated that the proposed rule denies protection to individuals who comply with medical advice by trying an on-formulary drug instead of the drug originally prescribed or by seeing their primary care physician rather than a specialist and subsequently experience an adverse reaction that triggered the disruptive behavior. Another commenter believed that, in cases where an individual is unstable, disruptive behavior could be related to unsuccessful attempts to find the proper medication or due to a plan's step therapy requirement.

Response: We agree with the commenter, and clarify in the final rule at § 422.74(d)(2)(i) that an individual's behavior cannot be considered disruptive if such behavior is related to the use of medical services or compliance (or non-compliance) with medical advice or treatment. For example, an individual who chooses to disregard medical advice, such as not heeding the advice to stop using tobacco products, is not exhibiting disruptive behavior.

Comment: Several commenters supported the flexibility afforded by allowing MA organizations to limit re-enrollment for individuals who are disenrolled for disruptive behavior. One commenter however, opposed the provision on the grounds that prohibiting an individual from re-enrolling in a plan for a specified period could cause undue harm.

Response: In the proposed rule, we specified that, under § 422.74(d)(2)(vi), an MA organization had the option to decline future enrollment by an individual who had been disenrolled for disruptive behavior. Although a prohibition on re-enrollment would still be possible under this final rule, we are not leaving this matter to the discretion of the MA organization. Instead, we are providing that an organization must request any future conditions on re-enrollment with their disenrollment request. We will then review each request on a case-by-case basis, consistent with § 422.75(d)(2)(v).

Comment: Several commenters submitted mix comments on the proposed expedited disenrollment process. Some commenters felt that the expedited process undermines the standards and requirements that are in place to protect beneficiaries, while other commenters supported the greater flexibility in cases where such behavior poses an immediate threat of health or safety to others.

Response: We believe that all individuals facing involuntary disenrollment for disruptive behavior must have sufficient opportunity, as provided by the notice requirements, to change their behavior and/or grieve the MA organization's decision to request involuntary disenrollment from CMS. Although we recognize that threatening behavior is a real, if rare, problem, we do not believe that expedited disenrollment is the appropriate remedy. Rather, we would recommend either a medical approach or, if warranted, a law enforcement solution for truly threatening situations. Therefore we are removing this provision from the final regulation.

Comment: One commenter recommended that the process for disenrolling AI/AN from MA organizations that contract with the HIs, an Indian Tribe or Tribal organization, or an I/T/U include direct communication with the I/T/U entity with adequate documentation of and steps taken to resolve the problem as well as adequate timelines.

Response: MA organizations have the statutory authority at Section 1851(g)(3)(B)(ii) of the Act to disenroll an individual from a plan if the individual has engaged in disruptive behavior and are required to provide sufficient notice to the individual in accordance with the timeframes specified in manual instructions. Because an individual is an enrollee of MA plan, the individual's relationship with the plan is primary. The MA organization, not the health care provider, is obligated to communicate with the individual or the individual's authorized representative as defined under State law. We believe that a provision requiring consultation with I/T/U entities would not be within the scope of the authority in section 1851(g)(3)(B)(ii) of the Act.

Comment: Several commenters submitted comments on whether nonpayment of cost-sharing should constitute disruptive behavior. Many commenters supported this interpretation, noting the negative impact that non-payment of cost sharing has on an MA organization's ability to provide or arrange for services for the individual. These commenters generally recommended that CMS establish a clear and uniform process for plans to follow. Another commenter suggested that such disenrollments be permitted only for certain types of services that represent significant portions of a member's overall cost-sharing responsibility. One commenter suggested that CMS establish a threshold of $2,000 of outstanding cost sharing, including two or more failures to pay cost sharing.

Other commenters, however, opposed including nonpayment of cost sharing as a basis for disenrollment. Some commenters stated that this policy would be discriminatory, placing very ill patients with high medical costs at a severe disadvantage and leading plans to cherry pick healthier patients. Another commented that CMS needed to take into account an individual who experiences a change in circumstances that may affect his or her ability to pay cost sharing.

Several commenters raised questions about how CMS would treat low-income individuals. Some commenters were supportive of a low-income exception for such disenrollments, while other commenters noted the administrative difficulty in applying the exception, since plans do not have mechanisms in place to determine beneficiary income levels or intervene on behalf on the enrollee with the provider.

Response: We appreciate the feedback provided on whether the nonpayment of cost-sharing should constitute disruptive behavior. We continue to believe that disenrollment for failure to pay cost-sharing may be disruptive under certain circumstances. At the same time, we believe that all the protections, such as notice requirements and case-by-case CMS review, should apply in these situations. Thus, we are not ruling out such disenrollment in certain cases, and we will consider these comments in developing guidance for the disruptive behavior provisions.

Comment: Other commenters recommended that CMS institute specific protections for individuals facing involuntary disenrollment, including an appeals process.

Response: Although we agree with the commenter that CMS should establish a procedure for beneficiaries to dispute enrollment denials, we do not believe that a formal appeals process is necessary. Instead, we intend to address beneficiary complaints regarding enrollment in a similar manner as we have done under the MA program. Under the MA program, individuals are advised through their notice of denial of enrollment that if they disagree with the decision, they may contact the MA organization. We provide assistance to MA organizations to handle beneficiary inquiries and complaints regarding enrollment through staff assigned to each MA organization. We envision a similar process being established under the PDP program.

10. Approval of Marketing Materials and Election Forms (§ 422.80)

We proposed to codify at § 422.80(a)(3) the ''file-and- use'' program already in place. This provision recognizes an MA organization's consistent compliance with marketing guidelines by providing for streamlined approval of marketing materials submitted by that organization. Organizations that have demonstrated to us that they continually meet a specified standard of performance are allowed to have certain types of marketing materials deemed to be approved by us if they are not disapproved within 5 days of submission to us for prior approval. In addition, the time frames under § 422.80(e)(5) were made consistent with those provided under § 422.80(a)(1). Lastly, we proposed clarifying changes to the discussion of prohibited marketing activities for MA plans.

Comment: Several commenters submitted comments regarding the ''file-and-use'' provisions. Many commenters supported incorporating this provision into the regulation and suggested that CMS consider even further flexibility as plans transition to the new Part D benefit in 2006. One commenter in support of the provision did note,

however, that small plans are more affected by the process since these plans submit fewer materials and a smaller number of errors impact their ability to participate. This commenter recommended that CMS consider this issue with regard to smaller organizations.

Many commenters opposed this provision and believe that the provision weakens the marketing rules and that MA organizations have not demonstrated that they deserve such a process. Given the new upcoming options and diversity of plan benefits, many believe stronger marketing requirements are needed. They were concerned that this process would perpetuate the perceived inconsistency in the marketing material approval process within CMS. Others were concerned that the short timeframe for CMS to review and approve would result in essentially CMS ''rubber stamping'' materials. One commenter suggested that plans present all marketing materials at least 30 days before proposed distribution.

Response: The ''file-and-use'' program streamlines the marketing review process while assuring that beneficiaries marketing materials are of a high quality and clarity. While we understand the concerns raised by smaller organizations, this program was developed to be available to those MA organizations that demonstrate they can consistently achieve a high level of performance with respect to producing accurate and clear marketing materials over a sustained period of time, regardless of the size of the organization.

It is also important to note that there are marketing materials that are not ''eligible'' to be considered under this program. Any marketing materials that describe benefits, cost sharing or plan rules are not eligible for the file-and-use status.

We retain the right to rescind file-and-use status from an MA organization if the organization fails to meet the rigid standards of compliance laid out in the file-and-use guidelines. We do not believe that the beneficiary is at greater risk as a result of the file-and-use program, but may actually benefit from being able to receive certain educational and outreach materials in a timely manner.

In response to the commenters seeking greater marketing flexibility, we also are providing in § 422.80(a)(2) of this final rule for organizations that are not currently eligible for the file-and-use method to use this method with respect to materials that pose the lowest risk of confusing or misleading beneficiaries. With respect to these materials, any MA organization may follow the file-and-use procedures if it certifies that it followed all applicable marketing guidelines, or that it used, without modification, model language specified by CMS.

Comment: One commenter expressed disappointment that CMS retained the prohibition on door-to-door solicitation. The commenter did not believe that retaining this ban was justified and the ban is outdated, since it was added 20 years ago when this activity was more difficult to monitor.

Response: We understand the need by MA plans to have additional flexibility in developing their marketing strategies. The purpose of this prohibition was to provide beneficiaries with appropriate beneficiary protections. Some individuals may not welcome unsolicited visits or may not be prepared to discuss their options, yet may feel pressured to do so. Given the complexity of the new programs and the upcoming limitations when individuals are able to make choices in their coverage, as well as increased competition, we believe that prohibition of door-to-door solicitation remains to be in the best interest of the beneficiary.

Comment: One commenter did not believe the regulatory language addressed the CMS timeline for review when materials are submitted after CMS' initial 45-day review period. Current guidance allows for an additional 45-day review period for CMS to review a document after it has been resubmitted. The commenter recommends instituting a 10-day review period for resubmitted materials.

Response: We appreciates this feedback and will take this under further consideration.

Comment: One commenter supported the extension of file and use to SNPs.

Response: Since SNPs are MA plans, all MA rules will apply to SNPs unless otherwise provided by us. Therefore, SNPs will qualify to participate in the file-and-use program provided the necessary requirements are met.

Comment: Several comments requested clarification from CMS that outreach workers employed by tribal and IHS facilities will continue to be encouraged to provide information about Medicare alternatives to the AI/AN elderly and this outreach would not fall under the prohibition against door-to-door marketing.

Response: We appreciate these concerns and will work with Tribal and IHS organizations to find solutions that both meet the needs of the AI/AN population and satisfy the requirements of the MA program.

Subpart C—Benefits and Beneficiary Protections

In the areas of benefits and beneficiary protections, we proposed regulatory reforms based on our program experience, as well as provisions implementing new requirements in the MMA. We tried to integrate new requirements in the MMA with existing regulations, while at the same time removing impediments in the existing rules that have tended to stifle innovation by M+C organizations. We believe our proposals addressed the paramount task of ensuring that beneficiaries continue to be fully informed and protected in their receipt of essential health care services under the Medicare program.

The regulatory reforms we proposed included: (1) New beneficiary protections related to receipt of covered health care services from contracted providers; (2) revisions to the rules limiting beneficiary cost sharing related to emergency episodes; (3) new rules affording additional protections to MA regional plans enrollees; (4) incentives for MA organizations to offer MA regional plans that would serve all beneficiaries in all areas; (5) the elimination of administratively burdensome requirements on MA organizations that are duplicative of other activities already conducted by us; and (6) the elimination of a number of unnecessary, duplicative, or overly burdensome access to care provisions.

We received hundreds of comments on subpart C from approximately 150 commenters in response to our August 3, 2004 proposed rule. Below we provide a brief summary of the proposed provisions and respond to public comments. (For a broader discussion of the proposed provisions, please refer to our proposed rule.)

1. General Requirements (§ 422.100)

MA MSAs are ''high deductible'' MA plans and are defined at section 1859(b)(3) of the Act. Until the deductible is met, the MA MSA enrollee is generally responsible for payment for all covered services. Once the MA MSA deductible is met, the MA organization offering the MSA plan is responsible for payment of 100 percent of the expenses related to covered services. In both cases, whether it is the enrollee or the MA organization offering the MSA that assumes responsibility for payment, providers and other entities are required to accept the amount that FFS would have paid (including permitted beneficiary cost sharing) as payment in full.

Section 233(c) of the MMA amended the Act to include enrollees in MSA plans offered by an MA organization with MA coordinated care plans as having protection from balance billing by noncontracting providers. In our proposed rule, we stated that for covered services provided to an MA MSA plan enrollee, a physician or other entity that does not have a contract with an MA MSA plan must now accept as payment in full the amount they could have collected had the individual not been enrolled in the MA MSA plan.

In the proposed rule, we specified that:

- The proposed provision applied to physicians and other entities. (Note that ''providers of services,'' as defined in section 1861(u) of the Act, are similarly restricted from balance billing MA MSA enrollees under section 1866(a)(1)(O) of the Act.)
- In cases in which Medicare participating physicians do not have an agreement with an MA organization in place governing the amount of payment, they must accept the amount they would have received under FFS Medicare as payment in full (including permitted beneficiary cost sharing).
- In cases in which Medicare non-participating physicians do not have an agreement with an MA organization in place governing the amount of payment, they also must accept the amount they would have received under FFS Medicare as payment in full (including permitted beneficiary cost sharing). (Medicare non-participating physicians are permitted to accept assignment on a case by case basis. For non-assigned claims, Medicare non-participating physicians are subject to the ''limiting charge.'')

These FFS charge limits have always applied to the charges that providers and other entities could impose when providing covered services to enrollees in MA coordinated care plans and private FFS plans, when there is no agreement with an MA organization in place governing the payment amount. The MMA added the same protections for MA MSA plan enrollees and we proposed conforming changes in subpart C and at § 422.214.

In addition to the new MA MSA ''charge'' protections, we proposed amending § 422.100 to provide for other changes for purposes of administrative simplification and clarification:

- We deleted the parenthetical ''(other than an M+C MSA plan)'' from the first sentence of § 422.100(b)(2) and replaced it with ''(and an MA MSA plan, after the annual deductible in § 422.103(d) has been met).''
- We modified the reference to ''additional benefits'' in § 422.100(c), as those benefits are no longer applicable to MA plans offered on or after January 1, 2006.
- We removed § 422.100(e) because it was duplicative, and we made the necessary redesignation changes.
- We removed the reference to operational policy letters in § 422.100(f).
- We added ''or encourage disenrollment'' to § 422.100(f)(2), after ''discourage enrollment,'' as one of the prohibitions on the design of benefit packages.

Comment: One commenter recommended that CMS clarify whether the proposed provider rules will now require providers accepting Medicare assignment to limit their charges to 100 percent of Medicare allowable costs for members of an MA MSA plan.

Response: The protections from physician balance billing that are described in section 1848(g) of the Act apply to all Medicare beneficiaries, including those enrolled in any type of MA plan. This includes enrollees of MA MSA plans. This means that for a Medicare participating physician, for instance, the billed charges cannot exceed the Medicare participating fee schedule amount for a Medicare-covered service. For Medicare non-participating physicians that do not accept Medicare assignment in a specific case, the charges cannot exceed 115 percent of the Medicare non-participating fee schedule amount for a Medicare-covered service.

Similarly, for providers of services, as defined at section 1861(u) of the Act, the participation agreement with Medicare requires the provider to accept the FFS payment amount as payment in full for services provided to Medicare beneficiaries, including those enrolled in any type of MA plan (see section 1866(a)(1)(O) of the Act).

Comment: A few commenters stated that CMS should clarify regulatory language to require MA plans to include statutory add-on payments under FFS Medicare to the noncontracting provider payments they are required to make under § 422.100(b)(2). Some commenters specifically mentioned such add-on payments (for example, DSH, outliers, GME, and IME payments) as part of the total payment amount that the provider would have received under original Medicare, and also including the balance billing permitted under Part A and Part B. Some commenters specifically mentioned the ''special'' hospital category payments for sole community hospitals, Medicare dependent hospitals, and critical access hospitals. Another commenter recommended that CMS clarify this ''new'' provision and asked why CMS made a distinction between providers of services, physicians, and other entities.

Response: This section of the regulation has been in place since the original M+C interim final regulation was published on June 26, 1998. In our August3, 2004 proposed rule, we simply added the billing protections for MA MSAs based on the amendment to section 1852(k)(1) of the Act provided in section 233(c) of the MMA. Otherwise, the distinction between providers of services, physicians, and other entities is statutory and based on the fact that noncontracting providers of services are required to accept Medicare payment rates from MA organizations based on section 1866(a)(1)(O) of the Act, while noncontracting physicians and other entities are required to accept Medicare payment rates from MA organizations based on section 1852(k) of the Act.

Additionally, we believe our regulation already requires FFS ''add-on'' payments (including those to both providers of services, physicians, and other entities), because they are generally considered part of the FFS payment that an MA organization must make to noncontracting providers, physicians, and other entities for covered services. However, an MA organization is not required to include IME and GME payments to noncontracting hospital providers to the extent the hospital providers receive IME and GME payments for MA plan enrollees directly from the fiscal intermediary (see § 422.214(b)). The fiscal intermediary's direct payments to hospitals of IME and GME amounts for MA enrollees are based on sections 1886(d)(11) and 1886(h)(3)(D) of the Act, respectively. Finally, § 422.100(b)(2) references the balance billing permitted under Part A and Part B of Medicare, which represents the maximum required payment due from the MA organization, less applicable MA enrollee cost sharing.

Comment: Several commenters recommended that CMS adopt blanket policies that would require MA and MA-PD plans to pay I/T/U facilities that serve AI/AN in a special manner. Among other proposals, these commenters suggested that CMS require MA organizations to waive cost sharing for AI/AN and that CMS require MA organizations to pay the ''full IHS Medicaid'' rate to I/T/U facilities, or that we establish other special payment methodologies related to MA reimbursement to I/T/U facilities.

Response: We are implementing the MMA statute through this rulemaking. The MMA did not provide for special

treatment under the MA program for AI/AN beneficiaries. For this reason, we do not see a statutory basis to apply different rules to a subset of Medicare beneficiaries, such as AI/AN populations. In general, however, we believe that MA regional plans will create new choices for beneficiaries, including AI/AN populations, and that access to MA plans will be improved. Similarly, because MA regional plans must reimburse for all covered benefits in and out of network, IHS facilities may receive reimbursement for out-of-network care provided to an MA regional plan AI/AN enrollee that they may otherwise not have been entitled to under the M+C program. However, the rate of reimbursement actually paid to an I/T/U facility for an AI/AN enrollee will vary based on the type of plan, type of service, and the plan-required level of enrollee cost sharing. For instance, for emergency department services, an MA plan enrollee's cost sharing would be limited to $50 and the MA organization (regardless of plan type) would be responsible for payment of the rest of the billed amount, up to the full Medicare rate. Similarly, an I/T/U, for an AI/AN MA PPO enrollee, could expect MA organization reimbursement for routine covered services provided to such an enrollee, although the amount of reimbursement directly provided by the MA organization would be limited to the full Medicare rate, less applicable enrollee cost sharing.

Finally, a broad waiver of beneficiary cost sharing of the type the commenters requested would not be permitted under provisions designed to protect the Medicare program from fraud and abuse. However, existing statutory and regulatory provisions may allow for the waiver of cost sharing in certain cases.

Comment: One commenter suggested that CMS require pre-approval before permitting an MA organization to adopt a local coverage determination for an MA regional plan under § 422.101(b)(4). This commenter also suggested that CMS require public comment on the choice of local coverage determination by an MA organization for either a local MA plan under § 422.101(b)(3) or an MA regional plan under § 422.101(b)(4).

Response: We do not interpret the statute at section 1858(g) to require CMS pre-approval of the local coverage determination an MA organization sponsoring an MA regional plan selects to apply to all enrollees of the MA regional plan. The statutory provision also does not include a requirement for public notice, but rather allows the MA organization to elect to have a local coverage determination apply to all enrollees of the MA regional plan. The MA organization must comply with applicable statutory and regulatory requirements in making such election, including the requirement, discussed below, that all local coverage determinations of the contractor selected by the MA organization be applied to the MA regional plan's enrollees.

Comment: One commenter recommended that CMS clarify whether or not MA organizations are required to provide all Medicare covered benefits in the MA plans they offer to Medicare beneficiaries. This commenter had specific concerns related to outpatient occupational therapy and whether a home visit by an occupational therapist to evaluate for safety and function post stroke, for instance, is a Medicare benefit that MA organizations have to offer enrollees of MA plans.

Response: Occupational therapy is a Medicare-covered outpatient benefit under section 1861(s)(2)(D) of the Act. Under section 1852(a) of the Act, an MA organization must provide all benefits under the original Medicare FFS program option. Therefore, MA plans must cover all services covered under Medicare Parts A and B.

Comment: One commenter stated that CMS is directed to ''replace'' Medicare carriers and fiscal intermediaries with Medicare Administrative Contractors (MACs) by section 911 of the MMA. The commenter asked what impact such a ''replacement'' would have on MA plans, which will likely cover larger areas than current FFS contractors.

Response: Transition from Medicare carrier and fiscal intermediary contractors to MACs is to occur between 2005 and 2011. We have modified the regulatory language in § 422.101(b)(3) to account for the transition to MACs by removing specific reference to Medicare carriers and fiscal intermediaries. We expect the impact this ''replacement'' will have on MA plans related to this section of the regulation will be insignificant. To the extent MACs will cover larger geographic areas than current FFS contractors, and to the extent MACs will apply local coverage determinations across those larger geographic areas, the opportunity for MA organizations to elect to apply uniform coverage rules in § 422.101(b)(3) or (b)(4) will also be likely to decline.

2. Requirements Relating to Basic Benefits (§ 422.101)

Section 221 of the MMA added a new section 1858(g) to the Act that provided for a special rule related to the way local coverage determinations (for example, ''local medical review policies,'' or ''LMRPs'') will be applied by MA regional plans. MA regional plans are permitted to elect any one of the local coverage determinations that applies to original Medicare FFS beneficiaries in any part of an MA region to apply to its enrollees in all parts of the MA region. Based on our interpretation of the statute, we proposed at § 422.101(b)(4) that an MA regional plan, if it chooses this option, must elect a single FFS contractor's local coverage determination that it will apply to all members of an MA regional plan. The MA organization would not be permitted to select local coverage policies from more than one FFS contractor that it would apply to all members of an MA regional plan.

Comment: A number of commenters recommended that CMS clarify the proposed language in § 422.101(b)(4). Some commenters recommended that CMS ensure that the understanding comported with ''the common understanding'' that regional plans can select coverage determinations issued by different intermediaries and carriers within the region. Some commenters also suggested that CMS extend the same flexibility to local MA plans. Others suggested that CMS allow MA organizations that sponsored multiple local MA plans to apply one FFS contractor's coverage determinations to its entire MA population.

Response: We disagree with the commenters who have requested the ability to select coverage determinations of multiple intermediaries or carriers within a region. As we stated in the proposed rule, our interpretation of section 1858(g) of the Act is that an MA regional plan exercising this option must elect a single FFS contractor group of local coverage determinations or policies that it will apply to all members of an MA regional plan and that an MA regional plan may not select local coverage policies from more than one FFS contractor. We are adopting this interpretation in the final rule.

The reason for this interpretation is two-fold. First, to the extent that local carrier and intermediary medical directors apply uniform experience to a broad range of coverage policies, it would be inappropriate to allow selection of a specific coverage policy from one carrier medical director and a different coverage policy on a different medical item or service from another carrier medical director. Second, to the extent that local carrier and intermediary coverage policies are generally statements of non-coverage, restricted coverage, or conditions for receipt of a specific health care item or service, it would be inappropriate to

allow an MA regional plan to adopt coverage policies issued by more than one carrier or intermediary. This interpretation would permit MA regional plans to deny coverage for what would otherwise be Medicare-covered services at a frequency and under conditions that no individual FFS beneficiary would ever face. For example, carrier ''X'' might have decided that Medicare coverage was not available for ''A'' in a local coverage area. Carrier ''Y'' might have decided that Medicare coverage was not available for ''B'' in a local area. In such a situation, were we to permit an MA regional plan to adopt the coverage policies of both carrier X and carrier Y, an MA plan enrollee of that regional plan would not have coverage for either A or B, while original FFS enrollees residing in carrier X's service area would have coverage for B, and those residing in carrier Y's service area would have coverage for A. Therefore, to emphasize these points and to correct the apparently common misunderstanding mentioned in the comment, we are modifying the language in § 422.101(b)(4). Further, the statutory language will not permit an extension to local MA plans of the requirement we are codifying in regulation at § 422.101(b)(4). Local MA plans whose service areas encompass more than one local coverage policy area will continue to be required to follow rules previously established for them in § 422.101(b)(3) based on statutory authority at section 1852(a)(2)(C) of the Act.

Finally, we respond to the commenters that asked whether an MA organization could apply a single FFS contractor's coverage determinations to its entire MA population and across local MA plans. Such a policy would not be in accord with the statute, which is specific as to both local and MA regional plans. The selection of a uniform coverage determination policy for both MA local and regional plans is available only at the plan level.

Comment: A commenter recommended that CMS revise the regulation at § 422.101(b)(4) in order to permit MA organizations that offer MA regional plans in more than one MA region to apply local coverage policies across regional boundaries.

Response: We are interpreting section 1858(g) of the Act as generally preventing such an interpretation or revision to the regulation. The statute specifically allows MA regional plans to apply coverage policies only from 'any part of such region.'' It would only be where one FFS contractor had a uniform coverage policy that straddled two regions, and where an MA organization offered MA regional plans in both of those regions, that such a result would be possible.

Comment: A commenter recommended that CMS allow an MA organization offering multiple local MA plans to apply the rule in § 422.101(b)(3) across MA local plans, or if local MA plans could adopt the new rule in § 422.101(b)(4) related to MA regional plans.

Response: The specific language at section 1851(a)(2)(C) of the Act is clear in not permitting such an interpretation or revision to the regulation. The statute specifically allows an MA organization sponsoring a local MA plan to apply the coverage determination most beneficial to enrollees from the service area of that local MA plan to all enrollees of that local MA plan, and subjects that to pre-CMS review before implementation.

Comment: A number of commenters pointed out the difficulty noncontracting providers will have ascertaining the local coverage policy that will apply to a specific MA regional plan enrollee. Some commenters suggested that CMS require MA regional plans to notify both enrollees and potential noncontracting providers of the LMRP that will apply to specific MA regional plan enrollees. Others stated that providers are most familiar with LMRPs that apply in the area in which they primarily practice medicine or provide services and that it will be difficult, if not impossible, to know whether a specific service will be covered for a specific MA regional plan enrollee when LMRPs are applied from different, and possibly remote, geographic areas. Some commenters pointed out the potential impact this would have on MA regional plan enrollees who could incur financial liability for services that are otherwise Medicare-covered in the geographic location in which they are provided. Many commenters stated that the problems related to knowing what LMRP applies to a specific MA regional plan enrollee are compounded by the fact that MA regional plan enrollees, as MA PPO enrollees, have the right to access all covered benefits (albeit at potentially higher cost sharing) from out-of-network providers.

Response: We have added a new paragraph to the regulation at § 422.101(b)(5) that will require MA organizations that elect to apply local coverage policies uniformly across a local MA plan's service area, or across an MA regional plan's service area, to inform enrollees and potential providers, including through the Internet, of the applicable local coverage policy that applies to the MA plan enrollees. This means that MA organizations choosing to avail themselves of the option of applying uniform LMRPs to a local or regional MA plan must create a web site upon which to post links to or copies of the applicable LMRPs. We believe that this requirement will not create a significant burden on MA organizations and will provide convenient access for both providers and enrollees to such information. We are also making a conforming change to § 422.111(f)(11) that requires MA organizations to notify providers through the Internet that such an election has occurred and what local coverage policy will apply to MA plan members.

We proposed to add a new § 422.101(d) to provide for new cost-sharing requirements mandated by MMA related to MA regional plans. There were three specific requirements:

1. MA regional plans, to the extent they apply deductibles, are required to have only a single deductible related to combined Medicare Part A and Part B services. Applicability of the single deductible may be differential for specific in-network services and may also be waived for preventative services or other items and services.

2. MA regional plans are required to have a catastrophic limit on beneficiary out-of-pocket expenditures for in-network benefits under the original Medicare FFS program.

3. MA regional plans are required to have a total catastrophic limit on beneficiary out-of-pocket expenditures for in-network and out-of-network benefits under the original Medicare FFS program. (This total out-of-pocket catastrophic limit, which would apply to both in-network and out-of-network benefits under original Medicare, could be higher than the in-network catastrophic limit, but may not increase the limit applicable to in network services.)

MA regional plans would be responsible for tracking these beneficiary out-of-pocket limits and for notifying members when they have been met. We also proposed to require MA regional plans to track and limit incurred rather than paid out-of-pocket expenses.

Comment: Many commenters recommended that CMS explain the significance of requiring MA regional plans to track ''incurred'' rather than paid expenses related to the deductible and caps on beneficiary cost sharing.

Response: There are two reasons for requiring MA regional plans to track incurred rather than paid beneficiary cost-sharing expenses. The first is that

we foresee a potential for disputes arising between providers and MA organizations related to the ''full'' reimbursement the MA organization will owe, once a cap had been met. If ''full'' reimbursement were not required until cost sharing had been paid (rather than incurred), then disputes might arise over what amount a beneficiary had actually paid in cost sharing, and when. Administratively, it is more feasible and less burdensome for plans to track incurred cost-sharing amounts than amounts actually paid, if for no other reason than the latter would require a feedback mechanism to the MA organization whenever an enrollee makes a payment of cost sharing. Second, it is possible that in many instances a beneficiary will be unable to pay full cost sharing for a service at the time of service. Many MA organizations, for instance, require inpatient hospital copays of more than $100 per day, even when in-network hospitals are used. Beneficiaries might need to pay cost sharing to providers over a period of time. Such delays in the actual payment of cost sharing should not affect the MA organization's responsibility for timely payment of claims.

Comment: A number of commenters recommended that CMS require MA organizations to make deductible and out-of-pocket information readily available to providers to facilitate billing at the time of service. Some commenters suggested requiring MA organizations to send notices of additional financial liability to enrollees on a monthly basis. Others suggested requiring that a standardized notice be used to ensure consistent reporting across all plans. Commenters also suggested requiring MA organizations to post enrollee deductible and catastrophic cap information on the Internet, so providers could easily and quickly determine enrollee liability at the time of service.

In addition, commenters suggested that CMS require MA organizations offering MA regional plans to provide information on deductible and out-of-pocket limits related to specific MA regional plan enrollees to hospitals, similar to the method by which hospitals are notified of Medicare beneficiary eligibility and Part A deductible status under the original FFS system. Others suggested that we require MA organizations offering MA regional plans to supply deductible and catastrophic cap information when health care providers and/or hospitals notify the MA organization that an MA plan member has presented for services.

Response: In response to these comments, we have modified § 422.101(d)(4) to indicate that notification to providers of enrollee status related to a deductible (if any) and catastrophic caps is also required. To the extent an MA regional plan enrollee is not aware of his or her deductible and/or cap status, the enrollee or a provider should have reasonable access to such information at the time of service.

Comment: A number of commenters recommended that CMS add a special provision for AI/AN to § 422.101(d) that would have the affect of requiring all MA regional plans to provide ''full reimbursement'' to all I/T/U facilities that treated enrollees of that MA regional plan.

Response: The MMA did not provide for special treatment under the MA program for AI/AN beneficiaries. For this reason, we do not see a statutory basis to apply different rules to a subset of Medicare beneficiaries, such as AI/AN populations.

Comment: A commenter generally supported the requirement at § 422.101(d)(4) that MA regional plans will be responsible for tracking the incurred beneficiary cost sharing related to the deductible and the catastrophic caps on beneficiary out-of-pocket expenses. The commenter expressed disappointment that a specific dollar amount or limit had not been set related to the caps on out-of-pocket expenses in § 422.101(d)(2) and (d)(3). The commenter also asked that we provide a definition of ''incurred'' costs that ensures that all cost sharing, whether paid by the beneficiary, or on his or her behalf, is counted and tracked.

Response: We did not establish maximum deductible or cap-levels in regulation, since the statute does not set such limits. We interpret the statute to allow for flexibility in plan design, within the constraints of statutory language, to promote competition. However, under our authority at section 1852(b) of the Act to disallow the offering of an MA plan where we determine that the plan design or its benefits are likely to substantially discourage enrollment by certain MA eligible individuals, we will review deductible and cap-levels to ensure that they do not substantially discourage enrollment. Additionally, as required by section 1854(e)(4) of the Act, beginning in 2006 (and for all MA plans other than MSA plans), the actuarial value of the deductible, coinsurance, and copayments applicable on average to individuals enrolled in an MA plan related to benefits under the original Medicare program may not exceed the actuarial value of the deductibles, coinsurance, and copayments that would be applicable on average to FFS Medicare enrollees related to benefits under the original Medicare program. As provided for in statute at section 1852(a)(1)(B)(ii) and in our regulation at § 422.101(e)(2), while the catastrophic limit on in-network receipt of benefits under the original Medicare program applies to the overall cost-sharing limit that an MA regional plan can impose per § 422.256(b)(3), the out-of-network catastrophic limit is not likewise constrained.

Finally and related to the tracking of incurred costs, we will require MA regional plans to track incurred as opposed to paid enrollee cost sharing. We will require MA regional plans to provide reimbursement to providers for covered services once the deductible or caps have been incurred regardless of who has actually paid the cost sharing, or for that matter, regardless of whether the deductible or other cost sharing has been paid at all. An MA organization with financial liability to reimburse a provider for covered services may not delay reimbursement until an enrollee first pays deductible or cost-sharing amounts.

The MMA also added a new section 1859(b)(4) to the Act requiring MA regional plans to provide reimbursement for all covered benefits, regardless of whether the benefits are provided within or outside of the network of contracted providers. As PPOs, MA regional plans are permitted to impose differential cost sharing related to non-emergency services received from non-network providers. To the extent differential cost sharing is part of the benefit package, the MA regional plan will generally be responsible for its portion of payment to a non-network provider, and the enrollee will be responsible for the remainder, up to the limits discussed above. We accommodated these requirements in the proposed rule at § 422.101(e).

MA PPO Benefits

We received many comments on § 422.101(d) and (e) related to the benefits and cost-sharing protections enrollees in MA regional plans can expect to receive. We also received comments specifically related to the definition of MA PPOs provided at § 422.4(a)(1)(v), which we responded to in the subpart A preamble above. Because of the interaction of the statutory and regulatory definitions of PPO (for both local MA plans and MA regional plans, which are offered as PPOs), and the benefits they must provide, we address a number of comments related to MA PPO benefits

in this section of the preamble that have a close bearing on the definition of MA PPOs.

As we stated in the subpart A preamble of the August 3, 2004 proposed rule: ''Section 520(a)(3) of the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) added section 1852(e)(2)(D) of the Act and defined PPO plans under the MA program for purposes of quality assurance requirements. As we discussed in the preamble to the final rule with comment period titled, ''Medicare Program; Medicare+Choice,'' published on June 29, 2000 (65 FR 41070), the definition of PPOs at section 1852(e)(2)(D) of the Act was explicitly for purposes of applying quality assurance requirements in 1852(e)(2)(B) of the Act and was limited in its applicability to paragraph (2) of section 1852(e) of the Act. Before the enactment of the BBRA, PPOs had been treated under the M+C statute and regulations in the same manner as all other M+C coordinated care plans for purposes of applying quality assurance requirements. In the June 29, 2000 final rule with comment period, we incorporated this new definition into the M+C regulations at § 422.4 and by revising § 422.152.

The PPO plan definition added by section 520 of the BBRA included three elements, they were as follows: (1) has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan; (2) provides for reimbursement for all covered benefits regardless of whether those benefits are provided within the network of providers; and (3) is offered by an organization that is not licensed or organized under State law as a health maintenance organization.

Because the definition of PPO plan in section 1852(e)(2)(D) of the Act only applies for the limited purpose of eligibility for PPO quality improvement requirements, we do not believe that the limitations in this definition should have been set forth in a generally applicable definition of PPO plan in § 422.4, as is currently the case. We propose to clarify in regulation that it is solely for purposes of the application of the more limited quality assurance requirements in section 1852(e)(2)(B) of the Act that PPOs must be offered by MA organizations that are not licensed or organized under State law as a HMO. For PPO-type plans that are offered by MA organizations that are licensed or organized under State law as HMOs, the quality assurance requirements that apply to all other coordinated care plans in section 1852(e) of the Act also apply to those PPO type plans.''

Based on this better interpretation of section 520(a)(3) of the BBRA, we proposed to modify the third element (related to State licensure) of the definition of MA PPO plan at § 422.4 to read as follows: ''A PPO plan is a plan that has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan; provides for reimbursement for all covered benefits regardless of whether the benefits are provided within the network of providers; and, only for purposes of quality assurance requirements in § 422.152(e), is offered by an organization that is not licensed under State law as an HMO.''

We also proposed to define MA regional plan at § 422.2 based on the definition in section 1859(b)(4) of the Act, which was added by section 221(b) of the MMA. The first and second elements of the definition of MA regional plan at section 1859(b)(4)(A) and (B) of the Act are identical to the first two elements of the definition of MA PPO plan at sections 1852(e)(3)(A)(iv)(I) and (II) of the Act , which was added by section 722(a) of the MMA. Note that the definition of MA PPO plan in section 1852(e)(3)(A)(iv)(I) of the Act is identical the definition of MA PPO plan that had appeared at section 1852(e)(2)(D) of the Act, as added by section 520(a)(3) of the BBRA. Therefore, the statute requires that both local MA PPOs and MA regional plans (which are offered as PPOs) must provide reimbursement for all covered benefits regardless of whether such benefits are provided within the network of providers.

Comment: Although some commenters supported, as a beneficiary protection, the fact that MA regional plans are required to provide reimbursement for all covered benefits, regardless of whether those benefits are provided within or outside the network of contracted providers. Many commenters suggested that statutory language requiring PPOs to provide reimbursement for all covered benefits should simply mean that PPOs need to provide out-of-network coverage for Medicare Part A and Part B services. The commenters also stated that they believe the statute never intended out-of-network coverage to apply to supplemental benefits, which are not part of the original Medicare benefit package.

Response: We disagree. The placement of the definition and other requirements related to MA regional plans in the MMA is instructive in this regard. As we noted earlier, section 221(b) of the MMA added the definition of MA regional plan, which includes the second element of the definition, ''that provides for reimbursement for all covered benefits regardless of whether such benefits are provided within such network of providers,'' at section 1859(b)(4)(B) of the Act. Section 221(c) of the MMA establishes ''Rules for MA Regional Plans'' by inserting a new section 1858 into the Act. In both, section 1858(b)(1) of the Act related to the single deductible that MA regional plans are permitted to apply, and section 1858(b)(2) of the Act related to the catastrophic limits that MA regional plans must apply, the statute is clear in stating that only ''benefits under the original Medicare FFS program'' are included. Where the intent is to limit application of MA plan requirements to only benefits under the original Medicare program (Parts A and B), the statute states such a limitation. Because no such limitation appears in either section 1852(e)(3)(A)(iv) of the Act, related to all PPOs, nor in section 1859(b)(4) of the Act, related to MA regional plans, we cannot apply such a limitation in the regulations.

Comment: Several commenters stated that benefits such as gym, eyewear, dental discounts, discounts on hearing aids, massage, acupuncture, weight control programs, or health-related magazines are unavailable out-of-network because as a practical matter, such benefits and discounts are negotiated and offered to MA organizations primarily in consideration of the guaranteed volume the exclusive service provider believes it will receive. Many commenters stated that, to the extent such discounted benefits are available from out-of-network service providers, the basis for the negotiated discount (guaranteed volume) becomes null and void.

One commenter stated that discount arrangements such as these, which secure a larger volume of business for the entity providing the discount, provide financial profits and are a common business model not limited to the world of health insurance. The commenter also stated that in these arrangements, there is typically no payment by the plan, and no cost sharing by the enrollee.

Response: Although we fully support discounts and volume purchasing where appropriate, it is important to note that discounts are not benefits under the MA program unless they meet the definition of ''benefits'' contained in the regulations. The definition of MA benefits is found at § 422.2 and reads as

follows: ''Benefits are health care services that are intended to maintain or improve the health status of enrollees, for which the MA organization incurs a cost or liability under an MA plan (not solely an administrative processing cost). Benefits are submitted and approved through the annual bidding process.'' Note that unless an MA organization actually pays for a health care item or service, the item or service is not a ''benefit'' of the MA plan. Therefore, negotiated discounts for services for which the plan incurs no cost or liability are not MA benefits, and are not subject to the requirement that PPOs provide reimbursement for all benefits, whether or not they are provided within the network of providers. That said, it is important to note that we have termed these types of negotiated discounts ''value added items and services,'' which are discussed in Chapter 3 (Marketing) of the CMS Medicare Managed Care Manual.

Comment: Some commenters stated that MA organizations frequently subcapitate ancillary provider networks (such as dental providers) and that such subcapitated arrangements make it difficult for the MA organization to provide reimbursement for all benefits, in- and out-of-network.

Response: The statute is clear that all MA organizations offering PPOs (local and regional) must provide reimbursement for all plan benefits in- and out-of-network. A number of MA organizations subcapitate Independent Practice Associations (IPAs), Physician-Hospital Organizations (PHOs), and similar subnetworks of providers, for most (or all) original Medicare Part B and/or Part A services. Such subcapitation arrangements are permitted within the MA program, subject to § 422.208 (the physician incentive plan requirements and limitations) and other statutory and regulatory provisions. However, to the extent an MA organization wants to offer a PPO (either local or regional), it will also need to make arrangements for providing reimbursement for all out-of-network benefits in such a subcapitated environment, or it will need to make arrangements with its subcapitated contractors for providing reimbursement for out-of-network benefits directly. Two points need to be made. First, the cost sharing that an enrollee will be required to pay when obtaining covered benefits out-of-network can be higher than the cost sharing that applies when services are obtained in-network. Second, to the extent that subcapitated arrangements make the provision of reimbursement for all benefits out-of-network impractical, an MA organization might consider offering an HMOPOS product, where out-of-network coverage and reimbursement can be limited in a number of ways.

Comment: Commenters stated that it would be impossible for plans to provide reimbursement for out-of-network receipt of benefits such as 24-hour nurse hotline services or disease management services.

Response: These services are not likely to be available from out-of-network providers because of the unique nature of the services and the integration between the plan and the service provider necessary for the delivery of such services. To illustrate, a provider of in-network disease management services to a plan's enrollees is likely to need access to plan and patient information in order to provide services to enrollees. An out-of-network disease management services provider would not have such access, and so would be unlikely to be able to provide the service out-of-network. Finally, to the extent that such services are available without cost sharing from in-network providers, the imposition of cost sharing of any amount for their receipt out-of-network should deter virtually all enrollees from seeking them out-of-network.

Comment: Some commenters pointed out the difficulty inherent in requiring MA-PDs that are offered as PPOs to provide reimbursement for mail-order drugs or Part D (prescription drug) benefits received by enrollees from out-of-network providers.

Response: As a practical matter, an MA PPO plan that offers Part D coverage as an MA-PD will need to provide out-of-network coverage of Part D drugs consistent with the requirements of the Part D program and the regulations at part 423.

Comment: A commenter stated that further complications might arise were CMS to interpret ancillary services (for example, dental and eyewear) as being services subject to the catastrophic limit on out-of-pocket expenses. The concern was that once an enrollee has met the out-of-network cap, cost sharing would no longer act as a deterrent to the unrestricted and ''free'' access by PPO enrollees to these benefits from out-of-network providers.

Response: The statute and our implementing regulations at § 422.101(d)(2) and (d)(3) are clear in limiting application of the catastrophic caps to Part A and Part B benefits. To the extent dental or eyewear benefits of an MA PPO plan are not also original Medicare benefits, cost sharing can continue to apply, even after the out-of-network additional catastrophic limit in § 422.101(d)(3) has been met.

Comment: A number of commenters recommended that we revise the proposed rule to clarify that MA regional plans may establish prior authorization requirements for services obtained out-of-network and that both MA regional plans and local PPOs should be permitted to offer certain services only through network providers, where, for instance, the services have unique characteristics. The commenters stated that private sector PPO benefits are commonly offered in this manner. Therefore, the commenters believe that by providing this flexibility, CMS would allow the offering of MA PPO plans and benefits in a comparable manner to those generally available to consumers, and that this will make it possible for them to continue to offer certain services that add value for beneficiaries.

Response: Although we support the offering of added value to beneficiaries where possible, as we have previously discussed, there is a clear statutory requirement that all covered benefits of an MA PPO plan (regional or local) must be available out-of-network. The statute provides a definition of PPO that may not, in all respects, conform with business models that might be present (or even prevalent) in the commercial sector. Unlike plans serving commercial populations, the Medicare program is primarily intended to serve aged and vulnerable beneficiary populations. Therefore, the dynamics of the MA program may not match those in the commercial market. Also, for all MA plans they offer, MA organizations are required to follow FFS coverage rules related to items and services covered under FFS Medicare. Although MA organizations are permitted to adopt a single local coverage policy that will apply to all enrollees in an MA plan, in accordance with § 422.101(b), MA organizations are not permitted to impose a more stringent test related to medical necessity determinations for Medicare-covered services than the one that applies under the FFS program.

For items and services not covered by Medicare that the MA organization provides under section 1852(a)(3) of the Act, similar considerations apply. In other words, to the extent and under the conditions that a non-Medicare supplemental benefit would be available to a plan enrollee within the network of providers, such a service would also need to be available to an MA PPO enrollee out-of-network. That is not to say that differential cost sharing cannot be applied to out-of-network receipt of covered services, nor does it mean that

out-of-network cost sharing cannot be differentially applied to specific services or types of services. We believe that MA organizations offering MA PPOs (both local and regional) can accomplish their business strategies while still working within the statute.

For instance, an MA PPO can warn enrollees that to the extent that an item or service is not a covered benefit of the plan, the enrollee would be required to pay the full cost of the service. This warning might have the desired effect of encouraging the enrollee to call the MA plan before seeking care out-of-network, as a means of ensuring that a specific item or service is actually a covered benefit of the plan. Similarly, for specific services for which the plan has established substantial out-of-network cost sharing, the enrollee can be encouraged to contact the plan for pre-authorization that would reduce cost sharing. For instance, for out-of-network receipt of a specific inpatient hospital service the normal cost sharing might be 40 percent of charges. To the extent an enrollee or provider calls and receives plan pre-authorization for a specific out-of-network hospitalization of this type, the MA plan might reduce enrollee liability to 20 percent (or less) of charges. MA PPOs must be able to provide coverage and medical necessity determinations to enrollees (and providers) before the enrollee receives out-of-network services. This will act as a beneficiary protection.

A prudent enrollee will have reason to ensure that such services are medically necessary and covered by the plan before self-referring to out-of-network providers. Similarly, a prudent provider will have a means of ensuring that plan coverage will be provided. However, the idea that a gatekeeper must provide a referral or that an MA plan must pre-authorize a service before it will be covered at all, or that such a referral or plan pre-authorization is a necessary condition for receipt of any medically necessary out-of-network plan covered service is not in accord with the statutory language pertaining to MA PPOs.

Our belief is that the statute precludes requiring a medical necessity determination, a plan pre-certification or pre-authorization, or a coverage decision before receiving a covered service out-of-network. As long as an MA PPO enrollee is willing to pay the higher cost sharing associated with out-of-network care, there can be no additional barrier to receipt of plan covered benefits. If an MA organization offering an MA PPO is particularly concerned with over-utilization or inappropriate utilization of services (or of a particular service) out-of-network, the organization has the authority to impose relatively high out-of-network cost sharing overall, or related to a specific service. Also note that to the extent a referral or plan pre-authorization has been provided for in-network care, the enrollee has the right to use the referral or plan pre-authorization for receipt of the same care out-of-network (with applicable out-of-network cost sharing).

Comment: A commenter recommended that CMS offer alternative regional PPO product designs, which the commenter called ''Performance Risk PPOs.'' The commenter included a proposal that would, offer plan incentives for higher quality, better customer service and benefits, improved outcomes and program savings, and penalize plans that do not perform well on these measures. The commenter explained that such a model would offer a range of out-of-network benefits, but not all Medicare-covered services would be available out-of-network. In addition, the commenter stated that although referrals would not be required for accessing out-of-network care, pre-certification might be required.

Response: Under the definitions of regional PPO contained in the MMA, the MA regional plan must provide for reimbursement for all covered benefits, regardless of whether such benefits are provided within the plan's network of providers. Therefore, a plan of the type that the commenter proposes would not meet the statutory definition of MA regional plan. Further, as we have stated above, plan pre-certification or pre-authorization may not be a necessary condition for receipt of out-of-network covered services.

3. Supplemental Benefits (§ 422.102)

In the August 3, 2004 proposed rule, we stated that an MA plan could reduce cost sharing below the actuarial value specified in section 1854(e)(4)(B) of the Act as a mandatory supplemental benefit. Beginning in 2006, an MA plan can reduce the cost sharing that applies to plan members below the actuarial value of the cost sharing that would apply to those members if they were enrolled in the original Medicare program. This amount is not just the limit on the amount of cost sharing that an enrollee can be charged in the plan's bid for Medicare Part A and Part B services (and for which and when such plan cost sharing exceeds FFS cost sharing, a supplemental premium is necessary), but it also expresses the value of the bid-based cost sharing when the bid is below the benchmark. When we reference section 1854(e)(2)(B) of the Act in § 422.102(a)(4), we are referring to the latter value, not the former. This reduction in cost sharing can be included as a mandatory supplemental benefit and was proposed at § 422.102(a)(4).

We also proposed the following conforming changes to § 422.102:

- We removed the reference to ''additional benefits,'' as those benefits are no longer applicable to MA plans offered on or after January 1, 2006.
- We removed the reference to operational policy letters (OPLs) in § 422.102(a)(3), as guidelines related to benefits that had been contained in OPLs have been incorporated into regulation, into the Medicare Managed Care Manual, or into other instructions.

We received no comments on this section, so we finalize it as proposed.

4. Benefits Under an MA MSA Plan (§ 422.103)

For clarification purposes, we proposed to remove the extraneous word ''under'' from paragraph (a) of § 422.103.

We received no comments on this section, so we finalize it as proposed.

5. Special Rules for Self-Referral and Point of Service Option (§ 422.105)

''Point of Service'' (POS) is an option in some plans that allows enrollees to obtain non-network services, with the plan providing some limited level of reimbursement for such services. To clarify an issue that has created confusion for both beneficiaries and MA organizations, we proposed to clarify at § 422.105 that if an MA organization does not offer a POS benefit to members of a plan (or if it offers a POS benefit as an optional supplemental benefit and the member has not selected that benefit), the member cannot be financially liable for more than the normal in-plan cost sharing for covered items or services from contracted providers.

We stated that we believed that indemnifying the Medicare member in such a situation conforms with normal industry practice and also clarified our long-standing policy that members cannot be held financially liable when contracting providers fail to follow or adhere to plan referral or pre-authorization policies before providing covered services. If a plan member insisted on receiving what would otherwise be covered services from a contracted provider (but for the lack of a referral or plan pre-authorization), then the contracted provider would be required to inform the member that those services would not be covered under the plan. We proposed to require

the provider to document the medical record as to why the services are medically necessary but not available through the plan.

In addition, an MA regional plan might choose to provide for a POS-LIKE benefit where beneficiary cost sharing would be less than it would otherwise be for non-network provider services, but where it still might be greater than it would be for in-network provider services, if an enrollee follows pre-authorization, pre-certification, or pre-notification rules before receiving out-of-network services. Note that such pre-authorization, pre-certification, or pre-notification cannot be a necessary condition for receipt of, or required MA plan reimbursement for, out-of-network covered services by a PPO enrollee; however, it can act as a financial incentive (by lowering the normal out-of-network cost sharing that would otherwise apply) to an enrollee to voluntarily participate.

In this final rule, the title of this section is being changed to emphasize the fact that it contains not only rules related to POS options or benefits, but that it also contains a rule related to enrollee self-referral to plan contracted providers in all MA plans.

Comment: Many commenters recommended that we clarify the meaning of the introductory statement proposed to § 422.105(a). Other commenters suggested that the statement was misplaced, because the proposed regulation would apply to plans with and without POS offerings. Others commenters stated that in plans in which a POS option was provided as a mandatory supplemental benefit, the introductory statement we proposed to add would have no effect and would therefore be confusing.

Response: We agree with the comments regarding potential confusion and have renamed the title of this section of the regulation and reorganized it to indicate that it covers not only POS offerings, but that it also applies to all situations in which an MA plan member self-refers to a plan-contracting provider, whether or not a POS benefit is involved.

Comment: One commenter stated that while some types of services may not be covered under any circumstances, other services might not be covered by an MA plan because they are not medically necessary or appropriate for the enrollee. The commenter suggested that CMS clarify the applicability of the introductory statement to circumstances in which a service does not meet coverage criteria based on medical necessity.

Response: Many commenters responded to our request for comment in the subpart M preamble of the August 3, 2004 proposed rule related to whether or not we should permit or require (and under what circumstances) advance beneficiary notices (ABNs) to be issued by network or non-network providers to MA plan enrollees. Many of the commenters opposed such a requirement as being overly intrusive on the patient and doctor relationship and other commenters supported it as being a valid and necessary beneficiary protection. We address the specific comments related to ABNs in the subpart M preamble of this rule.

Although we decided not to incorporate an ABN requirement into the MA program at this time, we believe that there is an important beneficiary protection at stake, especially in light of the projected growth in MA PPO enrollment due to the advent of the MA regional plan program. MA organizations have a responsibility to ensure that contracting physicians and providers know whether specific items and services are covered in the MA plan in which their patients are enrolled. If a network physician provides a service or directs an MA beneficiary to another provider to receive a plan covered service without following the plan's internal procedures (such as obtaining the appropriate plan pre-authorization), then the beneficiary should not be penalized to the extent the physician did not follow plan rules. MA plan enrollees cannot be held to a higher standard than plan contracting providers. To the extent a contracting provider performs a service or refers a patient for health care services that an enrollee reasonably believes would be covered services of the plan, then an MA plan enrollee cannot be liable for more than applicable plan cost sharing for those services. To the extent an MA organization does not properly inform contracted providers, or to the extent an MA contracted provider does not properly enforce referral procedures, then to that same extent, an MA plan enrollee cannot be held financially liable for the organization's or provider's failure. Under its contract with the MA organization, a provider is contractually bound to look solely to the MA organization for reimbursement for covered services (see § 422.502(g)(1) and § 422.502(i)(3)). Similarly, MA organizations are required to communicate clear and consistent coverage guidelines and medical management procedures to contracting physicians (see § 422.202(b)).

Comment: Some commenters recommended that CMS be more flexible and not require the network contracted physician or provider to document the medical record as to why the items or services were medically necessary but not available through the plan. These commenters suggested that it was inflexible to require that such documentation appear only in the medical record.

Response: We agree with this comment that it was overly proscriptive to require that such documentation could only appear in the medical record and will permit flexibility regarding where such information is documented. We have added language at the end of § 422.105(a) that does not specify where such documentation must reside.

Comment: A few commenters asked us to clarify the issue of the provider's ability to bill the beneficiary, if all actions specified in § 422.105(a) have taken place. Commenters stated that the clarification should specify the conditions under which they are permitted to bill a beneficiary. One commenter asked whether the rules established in this section of the regulation also apply to hospitals and other types of contracted providers.

Response: The intent of our revision to § 422.105 is to clarify a beneficiary protection and not necessarily to clarify under what conditions an MA-contracting provider may or may not bill an MA plan enrollee. As mentioned above, all contracting providers are bound to look solely to the MA organization for reimbursement for services covered under the MA plan in which a Medicare beneficiary is enrolled. To the extent an MA-contracting provider provides a non-covered service to an MA enrollee, then payment for such a service is not generally within the regulatory purview of the MA program.

However, where the enrollee is notified in advance by the contracted provider that a service will not be covered unless the beneficiary receives a referral or takes some other action, and that notification is documented, and the beneficiary receives the service without obtaining the referral or taking the necessary action, then the enrollee can be billed and may be held financially liable for the service. Additionally, even if a beneficiary is informed (either verbally or in writing) that a specific service will not be covered by the MA plan in which the beneficiary is enrolled, that beneficiary is entitled to appeal such a determination, whether or not the service is actually provided after such notification. Finally, § 422.105(a) applies to all contracted providers, including physicians, hospitals, and other provider types.

Comment: One commenter suggested that CMS was proposing an odd and fundamentally misguided rule governing members of MA plans who self-refer. Another commenter stated that the requirement was unnecessary, inflexible, and burdensome for contracted providers. The first commenter stated that the proposed rule contradicted fundamental managed care principles and that the proposed rule would shift payment responsibility from the self-referring member to the contracted provider and/or the MA organization.

The first commenter asserted that enrollees who self-refer should be required to pay the entire cost of the service and should not be rewarded by having to pay only the normal, in-network cost sharing. The second commenter stated that both contracting providers and MA plan enrollees are well aware when there is a requirement to secure a referral from a PCP before receipt of specialty care. Finally, both commenters stated that the proposed rule was flawed by not contemplating, or providing exceptions for, situations in which the service is not covered by the MA plan in which the individual is enrolled, or situations in which the service is not medically necessary.

Response: We do not agree. The language in § 422.105 states that only covered items and services are subject to the regulatory provision. Covered plan services do not include services that are inappropriate or not medically necessary for a specific individual in a specific situation. The intent of the regulatory provision is to limit patient liability in situations where a contracted provider provides a covered service, but for which certain technical, non-medical conditions of coverage have not been met.

Although we agree that the enrollee should not be ''rewarded'' for failing to follow proper plan pre-authorization or referral procedures, we also believe that the contracted provider and the MA organization also should not be ''rewarded'' by shifting financial responsibility to the enrollee for covered services that are actually the financial responsibility of the MA organization. The contracting provider is, or should be, aware of the MA plan's technical requirements for referral and/or plan pre-authorization related to covered services. If the contracted provider believes the covered service is medically necessary, then the contracted provider needs to explain the plan referral/pre-authorization process and should consider assisting the enrollee in obtaining necessary plan pre-service documentation. Finally, the contracted provider needs to inform the enrollee in instances when a service will not be covered unless the enrollee obtains a referral or plan pre-authorization and in which that enrollee will have full financial liability absent such referral or pre-authorization.

6. Coordination of Benefits With Employer Group Health Plans and Medicaid (§ 422.106)

Section 222(j) of the MMA revised section 1857(i) of the Act in order to facilitate employer sponsorship of MA plans. The MMA allowed us to waive or modify requirements that hinder the design of, the offering of, or the enrollment in an MA plan offered directly by an employer, a labor organization, or the trustees of a fund established by one or more employers or labor organizations to furnish benefits to the entity's employees, former employees, or members or former members of labor organizations. Section 222(j) of the MMA further stated that such an employer-labor organization sponsored MA plan may restrict enrollment to individuals who are beneficiaries and participants in such a plan. We proposed a new § 422.106(d) to account for this new statutory authority. (The August 3, 2004 proposed rule also contained a number of clarifying, conforming, and editorial changes to this section.)

Comment: One commenter recommended that CMS use the authority provided in section 1857(i)(2) of the Act to waive requirements related to MA regional plans. The commenter wanted to know if CMS would permit employer/labor sponsored MA plans that have been created for the sole enrollment of the sponsors' own employees, retirees, or members to participate in the MA regional plan stabilization fund or in risk-sharing through risk corridors, both described in regulation at § 422.458. The commenter was concerned that these special ''incentive'' payments for organizations sponsoring MA regional plans were primarily intended to foster the growth of MA regional plans for the enrollment of all eligible Medicare beneficiaries, and that it would be inappropriate to make such special payments to organizations offering plans that are only available for enrollment to employer/labor group members.

Response: We agree and have exercised this discretion under section 1857(i) of the Act to waive program requirements that facilitate employer/labor group enrollment. For instance, we have waived the requirement that MA organizations offer MA plans for enrollment to all Medicare Part A and Part B enrollees, and have allowed MA organizations to create plans that exclusively enroll employer/labor group members. We will continue to do so. However, we will not waive the ''general'' enrollment requirement that MA plans enroll all MA eligible individuals (see section 1851(a)(1)(A) of the Act) for either MA organizations or for employer/labor MA plan sponsors, if these entities seek to offer an MA regional plan solely to employer/labor group members.

Comment: The same commenter asked whether specialized MA plans for special needs individuals could be offered as MA regional plans.

Response: The statute is clear in saying that specialized MA plans for special needs individuals can be offered as any type of MA coordinated care plan (see section 1851(a)(2)(A)(ii) of the Act). MA regional plans are a type of MA coordinated care plan (see section 1851(a)(2)(A)(i) of the Act).

Comment: One commenter asked whether CMS would exercise the waiver authority under section 1857(i) of the Act in order to allow MA organizations to offer non-actuarially equivalent prescription drug coverage to MA plan enrollees who do not purchase Part D.

Response: We will not. Section 1860D–21(a)(1)(B)(ii) of the Act states that MA organizations may not offer prescription drug coverage (other than that required under Parts A and B of Medicare) to an MA plan enrollee unless it is qualified Part D prescription drug coverage.

Comment: One commenter asked if CMS would use the waiver authority to provide for special enrollment or conversion of enrollment rules for Medicaid beneficiaries enrolled in special needs plans, similar to what CMS have provided for employer/labor group members.

Response: As previously stated, we have waived the requirement that MA organizations offer MA plans for enrollment to all Medicare Part A and Part B enrollees, and have allowed MA organizations to create plans that exclusively enroll employer/labor group members. The authority for such waivers is contained in section 1857(i) of the Act and does not apply to individuals entitled to Medicaid. Note that section 1857(i) of the Act waiver authority is exclusive in its application to employees or former employees of an employer, or members or former members of a union, or a combination thereof. Waivers for individuals entitled to Medicaid are not provided for under the waiver authority in section 1857(i) of the Act. SNPs for Medicaid eligibles are authorized in section 231 of the

MMA. Finally, note that § 422.106(a) and (b) do not discuss employer/labor groups in the context of section 1857(i) waiver authority. Regulations related to employer/labor group waiver authority are exclusively discussed in § 422.106(c) and (d).

Comment: A number of commenters asked whether CMS would apply the new waiver authority in section 222(j)(2) of the MMA to AI/AN beneficiaries. The commenters stated that such a waiver might permit I/T/Us to sponsor MA plans exclusively designed for AI/AN beneficiaries.

Response: Section 222(j)(2) of the MMA added a new paragraph to the Act at section 1857(i)(2). This new provision created the opportunity for directly-sponsored employer/labor group MA plans. Section 1857(i) of the Act waiver authority is exclusive in its application to employees or former employees of an employer, or members or former members of a union, or a combination thereof. Waivers for AI/AN beneficiaries are not provided for under the waiver authority provided in section 1857(i) of the Act.

Comment: One commenter, in relation to a comment on § 422422.560 through § 422.626 (subpart M), recommended that CMS include benefits that are separately negotiated between the MA organization and an employer/labor group in the benefits governed by the MA regulations and therefore subject to the MA appeals and grievance processes.

Response: This comment has been addressed at greater length in the subpart M preamble. However, it is important to note that for purposes of subpart C, separately negotiated benefits between MA organizations and employer groups, labor organizations, and Medicaid (and as discussed in § 422.106(a)(a) and (b)) are not part of any MA plan. Such employer/labor/Medicaid benefits are discussed only in terms of the fact that they complement the benefits of an MA plan.

Comment: A commenter requested CMS to clarify that employer groups or labor organizations that become MA organizations may retain the services of entities to assist in the development and operation of the employer-sponsored MA plan. The commenter asked CMS to implement the waiver authority under Section 1857(i)(2) of the Act in a way that does not inadvertently hinder the efficient operation of support services for employer groups and labor organizations.

Response: We agree with the commenter that our waiver authority under 1857(i)(2) of the Act should be applied to allow employers and labor organizations to offer MA plans through arrangements with entities (such as existing MA organizations) that will facilitate the offering and efficient operation of such MA plans. We have revised § 422.106(d) to clarify this point and to clarify that, as provided in section 1857(i)(2) of the Act, we may exercise this authority on our own initiative as well as upon written request from an applicant. In each case, as specified in § 422.106(d)(3), our waivers and modifications will apply to all similarly situated MA plans.

Comment: A few commenters asked for specific waivers. Some commenters recommended waivers already provided, such as a waiver that would allow MA organizations to create separate MA plans solely for employer/labor group members.

Response: As we have done in the past, we will continue to provide specifics on approved waivers in guidance and in direct communication with waiver recipients, rather than in formal rulemaking.

7. Medicare Secondary Payer (MSP) Procedures (§ 422.108)

Section 232 of MMA amended section 1856(b)(3) of the Act to remove all ambiguity related to State authority over the MA program. The Congressional intent is now unambiguous in prohibiting States from exercising authority over MA plans in any area other than State licensing laws and State laws relating to plan solvency. We proposed to amend § 422.108(f) to remove language that suggests States can limit the amount an MA organization can recover from liable third parties under Medicare secondary payer procedures.

We received no comments on this section, so we finalize it as proposed.

8. Effect of National Coverage Determinations (NCDs) (§ 422.109)

Section 1853(c)(7) of the Act requires us to ''adjust'' MA payments when a national coverage determination (NCD) or legislative change in benefits will result in a significant increase in costs to MA organizations sponsoring MA plans. We historically interpreted what constituted ''significant'' costs in regulation at § 422.109, where the costs of a coverage change are considered ''significant'' if either the average cost of providing the service exceeds a specified threshold, or the total cost for providing the service exceeds an aggregate cost threshold.

In a final rule published in the **Federal Register** on August 22, 2003 (68 FR 50839), we amended § 422.109 to refine the definition of ''significant'' cost to include a new test. By adding a new paragraph at the end of § 422.109(a)(2), we provided that, for purposes of determining whether to make an additional payment adjustment under § 422.256, the tests for reaching the ''significant'' cost threshold were to include the aggregate costs of all NCDs and legislative changes in benefits made in the prior calendar year.

Under that new test, the ''average cost'' of every NCD and legislative change in benefits for the contract year would have been added together. If the sum of these average amounts exceeded the threshold under § 422.109(a)(l), then an adjustment to payment would have been made in the following contract year under § 422.256 to reflect this ''significant'' cost. Alternatively, if the costs of the NCDs and legislative changes in benefits, in the aggregate, exceeded the level set forth in § 422.109(a)(2), an adjustment to payment would also have been made under § 422.256 on that basis.

Among the reasons for the above change was that even when the ''significant'' cost threshold had been met under the existing definition, the methodology then employed for making a payment adjustment under section 1853(c)(7) of the Act did not result in an adjustment in the capitation rate in those counties with the ''minimum'' update rate (the ''2 percent minimum update'' counties paid under section 1853(c)(l)(C) of the Act.) In accordance with section 1853(c) of the Act, the CMS Office of the Actuary (OACT) used the annual growth rate to update only the floor and blended rates, so the ''minimum'' 2 percent update rate, which was 102 percent of the prior year's rate, did not reflect the costs of new benefits effective in the middle of the previous payment year. Therefore, we decided that payments in counties in which payment was based on the ''minimum'' 2 percent update rate were not appropriately adjusted to reflect new coverage costs as required by section 1853(c)(7) of the Act.

The MMA changed the ''minimum'' percentage payment prong of the former M+C payment methodology by adding a new basis for a minimum update. The ''minimum'' percentage increase rate is changed, effective January 2004, as follows: Instead of being set at 102 percent of the prior year's rate, the minimum increase rate will now be the greater of 102 percent of the prior year's rate, or the annual MA growth percentage. This means that under the MMA payment methodology, the minimum percentage increase will now reflect the cost of mid-year NCDs and legislative changes in benefits. These

costs are now automatically built into the annual MA growth percentage and will no longer require an additional adjustment under § 422.256.

As a result of these MMA changes to the MA payment methodology we proposed in the August 3, 2004 proposed rule to remove the portion of § 422.109(a)(2) after § 422.254(f).

We also proposed clarifying language in § 422.254(f) and § 422.109(c)(3).

We received no comments on this section, so we finalize it as proposed.

9. Discrimination Against Beneficiaries Prohibited (§ 422.110)

We proposed to correct § 422.110(b) to bring it into conformance with § 422.50(a)(3)(ii). Specifically, we proposed to modify the language of § 422.110(b) to state that if an MA organization chose to apply the rule in § 422.50(a)(3)(ii), and allowed individuals who are enrolled in a health plan at the time of first entitlement to Medicare, but residing outside the MA plan's service area to remain enrolled, the MA plan must also allow this for individuals with ESRD.

We also proposed to remove § 422.110(c), since it is duplicative of a requirement now appearing in § 422.502(h).

We received no comments on this section, so we finalize it as proposed.

10. Disclosure Requirements (§ 422.111)

Section 1851(d)(2)(A) of the Act and § 422.111(d)(2) establish disclosure requirements. MA plans must provide notice to plan members of impending changes to plan benefits, premiums, and copays in the coming year so that plan members will be in the best position to make an informed choice on continued enrollment in or disenrollment from that plan. We proposed to amend this section to reflect that notice must be provided at least 2 weeks before the Annual Coordinated Election Period commences, instead of listing a specific date in order to provide flexibility in the event that the beginning date of the Annual Coordinated Election Period changes in the future.

We also proposed to remove § 422.111(f)(4), as the requirement to provide information on Medigap and Medicare Select plans is a Secretarial responsibility under section 1851(d)(2)(A)(i) and (d)(3)(D) of the Act and is to occur as part of the ''open season notification'' required by section 1851(d)(2)(A) of the Act.

In addition to an ''open season'' notification, information on Medigap and Medicare Select is available year-round from the Federally funded SHIP and the 1–800 MEDICARE telephone number. Both the local SHIP and the 1–800 MEDICARE telephone numbers are prominently displayed in MA plan literature. In addition, we stated that we would continue to require MA plans to publicize the availability of information on Medigap, Medicare Select, and other MA plans through appropriate CMS information channels (for example, *www.Medicare.gov*, 1–800–MEDICARE). This not only would remove an unnecessary administrative burden, but also would ensure that reliable, accurate, and complete information is made available to those seeking it.

To accomplish the above proposed changes, we proposed conforming organizational changes to § 422.111. We also proposed the following disclosure requirement changes:

- We removed the requirement that MAs and MSAs provide comparative information related to other MA plans.
- To prevent what might otherwise be the unreasonable result that MA regional or national plans would be required to provide comprehensive lists of contracting providers to all enrollees, we modified paragraph (b)(3). (We specifically proposed to require MA organizations, however, to provide information on contracted providers in other parts of the plan's service area upon request in § 422.111(f)(10). Note that we changed the specific wording of this paragraph to more plainly express our intent and in response to comments, as described in further detail below.)
- We modified paragraph (b)(3) to read: ''The number, mix, and distribution (addresses) of providers from whom enrollees may reasonably be expected to obtain services;≥
- We added a new paragraph (f)(10), which reads: ''The names, addresses, and phone numbers of contracted providers from whom the enrollee may obtain in-network coverage in other parts of the service area.''
- At § 422.111(b)(11), we proposed to require MA regional plans to provide members an annual description (at the time of enrollment and annually thereafter) of the catastrophic stop-loss coverage and single deductible (if any) applicable under the plan.
- We changed the existing paragraph (f)(11) (the new paragraph (f)(9)) related to supplemental benefits.
- We also said that we were considering a requirement that all MA organizations sponsoring MA plans would be required to maintain plan-specific information on Internet web sites. We discuss this in more detail below.

In § 422.112(a)(1)(ii), we provide an ''exception'' to the requirement in § 422.112(a)(1) related to contracted provider networks in MA regional plans. We received a number of comments on this ''exception'' and address them later in this section of the preamble. We also explain later in this preamble why we are establishing a new beneficiary notification requirement related to enrollees of MA regional plans in § 422.111(b)(3)(ii). This new MA regional plan notification requirement is intended to parallel a similar OPM requirement imposed on the FEHB Blue Cross and Blue Shield Basic Option plan, which addresses similar circumstances and situations encountered by Federal employees and annuitants when seeking health care.

We have added a new paragraph to the regulation at § 422.101(b)(5) that will require MA organizations that elect to apply local coverage policies uniformly across a local MA plan's service area, or across an MA regional plan's service area, to inform enrollees and potential providers of the applicable local coverage policy that applies to the MA plan enrollees. We make conforming changes to § 422.111.

Comment: A commenter recommended that CMS explicitly state in the disclosure requirements related to MA plans that there were additional disclosure requirements under Part D with which MA-PD plans would also need to comply.

Response: We accept this comment. Although such a requirement is implicit in § 422.111(a)(2), where we require MA plans to disclose the ''benefits offered under the plan,'' we will explicitly state the requirement at § 422.111(a)(2). To the extent an MA plan offers Part D to its MA enrollees as an MA-PD plan, it will also be required to follow the disclosure requirements in § 423.128 related to the disclosure of its Part D offering.

Comment: A commenter recommended that CMS more directly address the ''free access'' MA enrollees have to Medicare hospice services and the fact that MA enrollees have the right to continue to receive non-hospice services, unrelated to the terminal illness, from the MA plan. The commenter wanted to ensure that MA enrollees knew that they could continue to receive from the MA plan non-hospice services unrelated to the terminal illness, as long as enrollees remain members of the plan.

Response: We do not believe a specific disclosure requirement of the type the commenter requests is necessary because our existing regulations already require disclosure of Medicare hospice availability, rules related to receipt of care, and financial responsibility, in § 422.111(b)(2)(iii) and

§ 422.320(a) (formerly codified at § 422.266(a)). Otherwise, because non-hospice benefits of an MA plan continue to be available after hospice election and while an individual remains enrolled in an MA plan, such availability must be disclosed under § 422.111(b)(2).

Comment: Several commenters recommended that CMS require MA organizations to inform beneficiaries about their benefits or restrictions on those benefits. For example, one commenter suggested providing information on the average number and type of home health visits per episode that were covered by an MA plan during the prior year and beneficiaries' average cost sharing; the names of home health providers in the plan's network and the number of years the provider has operated as a Medicare home health agency.

Response: We agree that disclosure of MA plan benefits continues to be an important feature that permits beneficiaries to make informed decisions on enrollment. As previously stated, MA plans are obligated to disclose information on benefits, including applicable conditions and limitations on their receipt, the plan premiums, and the cost sharing related to specific benefits when obtained both in- and out-of-network. We also require MA organizations to disclose information on the number, mix, and distribution (including addresses) of providers from whom enrollees may obtain services. These disclosure requirements are described in regulation at § 422.111 and have not materially changed. Although MA plans are not required to specify the average number of visits or types of visits per episode from the prior year, as the comment suggests, the plans are required to provide all covered home health services, which include, at a minimum, the Medicare FFS level of benefits. We will not require MA plans to specify the number of years a home health agency has operated, nor the other specifics that the comment suggests because this would impose an additional burden upon plans that we think in unnecessary in light of the existing ways in which beneficiaries can obtain such information.

The requirement that a plan disclose the name(s) and address(es) of the contracting home health agency or agencies is already set forth in our regulations at § 422.111(b)(3), redesignated as subparagraph (i). The additional information about which the commenter suggests requiring disclosure may be available, upon request, from either the MA plan or through a direct request to the contracting home health agency or agencies.

Comment: Several commenters noted the deletion of the word ''written'' from the first sentence of § 422.111(e). One commenter stated that removing the word might allow an MA organization to meet this disclosure requirement by simply posting information on its web site.

Response: The deletion of the word ''written'' was unintentional. We have reinserted it in the regulations text at § 422.111(e). We will continue to require MA organizations to make a good faith effort to notify members in writing of changes in provider networks.

Comment: A commenter recommended that we convey the language in § 422.111(f)(10). The commenter asked if the intent of paragraph (f)(10) was to complement the requirement in § 422.111(b)(3)(i) that routine disclosure of contracting providers was limited to those from whom an enrollee would ''reasonably be expected to obtain services.'' The commenter suggested that the language in paragraph (f)(10) was imprecise, if that was our intent, since it required disclosure, upon request, of other providers ''in other areas,'' although we may have actually meant to convey the disclosure, upon request, of contracted providers ''in other parts of the service area.''

Response: We agree with this comment and have corrected the language in § 422.111(f)(10). Our intent was to make information on the availability of other contracted providers in other parts of the service area of the MA plan available to plan enrollees upon request, to the extent such information was not provided at the time of enrollment, because of the large geographic area encompassed within the service area of the MA plan.

Comment: Some commenters opposed the deletion of § 422.111(f)(7)(i) through (iv) that eliminates the requirement that MA PFFS and MSAs plans provide comparative information related to other MA plans that are available in the geographic area in which the PFFS and MSAs plans are offered. These commenters stated that potential MA enrollees should be able to easily see how these plans compare to other MA plans and original FFS Medicare.

Response: We agree that individuals considering enrollment in an MA MSA or PFFS plan should have comparative information regarding their choices for receiving Medicare coverage. All MA plans, including MA MSA and PFFS plans, must continue providing comparative information on FFS Medicare through pre-enrollment materials including the Summary of Benefits. The Summary of Benefits contains a matrix that provides a comprehensive comparison of the benefits of an MA plan with the benefits of original FFS Medicare. As we discussed in the August 3, 2004 proposed rule, we believe that the *Medicare and You Handbook* in conjunction with other CMS information channels (such as the 1–800 MEDICARE call center and direct beneficiary counseling provided through federal SHIP grants to the states) provides the best opportunity for Medicare beneficiaries considering MA plan enrollment to receive clear, impartial, and complete information on the choices available to them. Therefore, we will delete these requirements, as they represent an unnecessary administrative burden on MA MSA and PFFS plans.

Comment: Some commenters suggested including a provision in § 422.111(e) that would allow AI/AN to switch to another MA plan whenever there is a change to the provider network of the MA plan in which the AI/AN is enrolled.

Response: We cannot accommodate this request because there is no statutory basis for differentiating between AI/AN and non-AI/AN beneficiaries. However, to the extent that conditions in § 422.62(b), where special election periods are discussed, are present for *any* MA plan enrollee, the opportunity to switch plans or to return to original FFS Medicare is available.

Comment: One commenter recommended that CMS remove the annual requirement for distribution of network provider directories. The commenter stated that for a vast majority of enrollees, the provider directory is not referenced and the information could more reasonably be made available on an ''as requested'' basis after initial provision upon enrollment.

Response: Under section 1852(c)(1)(C) of the Act, MA organizations are required to provide annually, in clear, accurate and standardized form, detailed information about the number, mix and distribution of plan providers. We have interpreted this requirement in regulations to include annual disclosure of plan providers' addresses.

Comment: Most commenters supported the new language in § 422.111(b)(3)(i). A few commenters recommended that CMS define or explain the statement, ''MA organizations would be responsible for providing the number, mix and addresses ''of providers from whom

enrollees may reasonably be expected to obtain services.'' One commenter suggested that the language was unclear, subject to broad interpretation and would result in confusion and an inconsistent application by MA organizations.

Response: We believe that the standard of ''reasonable'' disclosure of network providers is both appropriate and sufficiently clear within our current regulatory standards. We believe that MA organizations are in the best position to determine what would be ''reasonable'' in this context, based on service usage and community patterns of care. In order to preserve flexibility for MA organizations to provide information appropriate to the needs of their enrollees, we do not intend to change the proposed language in § 422.111.

Comment: A number of commenters recommended that CMS apply special disclosure requirements to AI/AN beneficiaries, stating that such special disclosure requirements should include a right by AI/AN beneficiaries to select another MA plan at any time without penalty.

Response: We cannot accommodate this request because there is no statutory basis for differentiating between AI/AN and non-AI/AN beneficiaries.

Internet

In the August 3, 2004 proposed rule, we asked for comments on whether or not we should require all MA organizations for all MA plans they offer to set up an Internet web site that would make basic MA plan information and materials available to interested Medicare beneficiaries and other parties. The basic information and materials could include the Evidence of Coverage, the Summary of Benefits, and information (names, addresses, phone numbers, specialty) on the network of contracted providers. Those Internet materials and information would duplicate materials already produced in print format and made available by MA organizations relative to the MA plans they offer.

Comment: Many commenters stated that it would be difficult for providers to know whether an MA organization had chosen to adopt one of the uniform coverage policies in § 422.101(b)(3), related to local MA plans, or § 422.101(b)(4)—related to MA regional plans.

Response: As we discuss at more length earlier in this preamble related to § 422.101(b)(3) and (b)(4), we agree with this comment and therefore have added a requirement at § 422.111(f)(11) that MA organizations must make uniform coverage policies related to an MA plan readily available to members and providers, including through the Internet.

Comment: Many commenters were supportive of the proposed requirement that all MA organizations provide basic materials, such as the Evidence of Coverage, Summary of Benefits, and information (names, addresses, phone numbers, specialty) on the network of contracted providers. Some commenters suggested that CMS not be overly prescriptive in the requirements for what MA organizations post to a web site. Some suggested that the provision of information over the Internet should relieve MA organizations of their responsibility to provide identical information to enrollees in hard-copy format. One commenter suggested that CMS make plan enrollees ''opt-in,'' if they want plan information sent to their homes.

Other commenters stated that most Medicare beneficiaries do not have access to the Internet, and that regardless of whether an MA organization provides plan information electronically, we should continue to require MA organizations to send enrollees required information through the mail. One commenter stated that it did not want its member handbook or Evidence of Coverage to appear on the Internet. The commenter stated that it would prefer to have the documents available only to members. Other commenters stated that requiring an MA organization to duplicate materials such as the Evidence of Coverage or the Summary of Benefits on the Internet would be administratively redundant, costly, and burdensome to maintain. One commenter suggested leaving the decision on an Internet web site to the discretion of the MA organization. This commenter stated that although it supports use of the Internet, MA organizations should not be required to post specific documents to the Internet, since they are already provided to enrollees in hard copy.

Response: Based on these comments, we will be as flexible as possible, while still ensuring that beneficiaries receive the information necessary to make informed choices. We will require MA organizations exercising options under § 422.101(b)(3) or (b)(4) to communicate, via the Internet and through other means, the fact that a specific local coverage determination is in effect for its plan members. We have placed this requirement at § 422.111(f)(11). Use of the Internet in this way will ensure that potential providers have access to plan coverage information to the extent that it differs from the Medicare coverage policy in the geographic area in which the provider is actually treating an MA plan enrollee. Similarly, we will require MA organizations that have Internet web sites to post the Evidence of Coverage, the Summary of Benefits, and information on the network of contracted providers at § 422.111(f)(12). Because we apply this requirement only to organizations that otherwise maintain Internet web sites, we do not believe that such a requirement is overly burdensome or that it will entail a significant administrative effort. In addition, because the Evidence of Coverage and the Summary of Benefits do not change during the course of a calendar year, maintaining or updating the information in them will be a once-a-year activity, which will coincide with the update of the hard copy version of these documents. Updating of the provider directory might entail additional administrative effort; however, to the extent that MA organizations are already required to update provider information in written materials, we do not believe that extending this requirement to an electronic version of the same document would entail a great deal of additional administrative effort.

In response to the commenters that asked if the use of Internet versions of required documents would eliminate (or mitigate) the requirement for hard copy documents, we have added a final sentence to § 422.111(f)(12) that states that we will maintain our current requirement that MA organizations provide to enrollees written, hard copy materials providing information at the time of enrollment and annually thereafter as required by § 422.112(a) and (b). Most Medicare beneficiaries do not routinely use the Internet. To the extent they do and do not wish to receive hard copy plan materials, they can and will indicate such a preference. In response to commenters who did not believe it appropriate to post plan materials to the Internet, we respond that we believe it is an important feature of beneficiary choice to be fully informed regarding the benefits and features of an MA plan *before* enrollment. Plan materials, including the Evidence of Coverage, the Summary of Benefits, and a list of contracting providers are essential pre-enrollment materials that allow Medicare beneficiaries an opportunity to compare MA plans and to make an informed decision on enrollment.

11. Access to Services (§ 422.112)

There are no new access standards for MA regional plans, and existing MA standards will generally apply. We

reviewed our existing regulatory requirements related to network adequacy and proposed to remove some that are either duplicative or, in our view, overly onerous. We stated we expected competition to be the best method for ensuring network adequacy, as enrollees will favor and enroll in plans with more extensive networks and tend to avoid those without. Furthermore, Medicare beneficiaries can always choose to remain enrolled in the original Medicare FFS program.

We proposed to remove or modify some the requirements from § 422.112 of the regulation, none of which were required by statute, and some of which became unnecessary as they were replaced or superseded by requirements in the MMA:

- We proposed to delete § 422.112(a)(4), because we believed it would be redundant to suggest a specific approach to quality improvement activities in the context of, and as a means of ensuring, enrollee access to care. After reviewing and responding to comments (below), we will implement as proposed and delete § 422.112(a)(4).
- We proposed to remove the written standards requirements in § 422.112(a)(7) since they were duplicative of other provisions in the regulation. Based on a comment we received, we will not delete the requirement.

In the final rule we make editorial corrections to § 422.112(a) heading and introductory text to remove reference to ''network M+C MSA plans'' and ''additional'' services, neither of which terms have relevance in the MA program.

Comment: We received a few comments related to our proposal to remove requirements in § 422.112(a)(7). One commenter asked us to articulate what tools, other than written standards, an MA plan should use to ensure adequate access to medically necessary health care items and services. Other commenters objected to removal of written standards.

Response: Written standards are simply one aspect of an MA coordinated care plan's guarantee of access to care. Such written standards do not, in and of themselves, constitute a sufficient guarantee of access to care. To the extent that written standards are not enforced, they guarantee little. However, we agree with the commenters and believe that the requirement for written standards will, at the very least, prompt plans to affirmatively address and memorialize how they intend to provide access to care. In light of the comments we received and upon further consideration, we will retain the requirement for written access standards in § 422.112(a)(7).

Comment: One commenter recommended that CMS modify the rules to create waivers that would allow ESRD patients to be referred to nephrologists, dialysis centers, or vascular surgeons who are out-of-network if the patient prefers another physician or center, or if the referring nephrologist believes that the vascular access outcomes would be better with the out-of-network surgeon. The commenter also suggested allowing self-referrals to specialists, such as allowing ESRD patients to self-refer to nephrologists, dialysis centers, or vascular surgeons who were out-of-network. Another commenter suggested including certain benefits in the MA benefit package, such as medical nutrition therapy (MNT) benefits for diabetes and renal diseases.

Response: To respond to the first comment on the provision of benefits to ESRD beneficiaries out-of-network, PPOs are a type of coordinated care plan, as described in § 422.4(a)(1)(iii), that are required to provide reimbursement for all covered benefits regardless of whether they are provided in- or out-of-network. Therefore, a beneficiary with ESRD who is enrolled in an MA PPO plan may go out-of-network for all covered services, albeit with a potentially higher cost-sharing liability. Coordinated care plans are permitted to use mechanisms to control utilization, such as requiring referrals from a ''gatekeeper'' PCP, before an enrollee can receive in-network specialty services at in-network cost sharing levels, as codified in regulations at § 422.4(a)(1)(ii)and § 422.112(a)(2). Therefore, access to a specialist at in-network cost-sharing levels can generally be limited to contracted providers in coordinated care plans. When an individual beneficiary chooses a coordinated care plan, information is available about the availability of providers, including specialists, and under what conditions they are available in-network. Information on the routine availability of out-of-network care (either because the plan is an HMOPOS or a PPO, for instance) is also provided at the time of enrollment and annually thereafter. On the second point related to requiring MNT benefits for diabetes and renal diseases in MA plans, we remind the commenter that all MA plans are required to include all Medicare FFS benefits in their MA plan benefit packages.

Comment: One commenter recommended that CMS require all MA plans to include podiatric physicians in their networks to ensure that the necessary and vital services provided by these physicians continue to be available to patients. The commenter stated that § 422.205(a) prohibits MA organizations from discriminating against providers on the basis of license or certification.

Response: We do not see a basis for requiring MA organizations to contract with a specific provider type. As the commenter stated, our existing regulations prohibit discrimination on the basis of license or certification. Further, our existing regulations, as amended in this final rule, require MA organizations to ensure that covered services are available and accessible within an MA plan's network consistent with applicable access standards. However, § 422.205(b), which is not being amended in this rule, allows MA organizations to refuse to grant participation to health care professionals in excess of the number necessary to meet the needs of an MA plan's enrollees (with the exception of PFFS plans).

Comment: One commenter agreed that the requirements in § 422.112(a)(4) are duplicative of the proposed chronic care improvement requirements in § 422.152(c), and therefore generally agreed that it should be deleted. However, the commenter also stated that deletion of requirements at § 422.112(a)(4) should be made contingent on our addition of a requirement in § 422.152(c) that chronic care improvement programs be based on objective and evidence-based criteria, such as clinical practice guidelines.

Response: We address comments related to § 422.152(c) in the subpart D section of the preamble (below). Because chronic care improvement programs will be regulated under the provisions in subpart D of the 42 CFR part 422, we believe it remains appropriate to delete regulatory requirements concerning complex or serious medical conditions from § 422.112(a)(4).

Comment: One commenter asked whether access to covered MA plan services can be denied, if the MA plan enrollee does not pay plan required cost sharing at the time of service.

Response: The MA organization's responsibility for provision of plan covered services supersedes the member's responsibility for payment of cost sharing at the time of service. Therefore, the MA organization cannot deny provision of a medically necessary covered service for want of the payment of applicable cost sharing at the time of service.

Comment: One commenter stated that CMS should add a provision in the regulation that would apply section 1861(s)(2)(H) of the Act to MA plans offered by MA organizations.

Response: We do not agree. Both section 1861(s)(2)(H)(i) and (ii) of the Act are specific in their applicability to contracts under section 1876 of the Act. Contracts with MA organizations for MA plans are under section 1857 of the Act.

Continuity of Care

Section 422.112(b) requires all MA organizations for all MA plans they offer to ensure continuity of care through integration of health care services. Additional requirements in § 422.112(b)(1) through (b)(6) require specific methods by which MA organizations are to ensure an effective continuity and integration of health care services. Although all of the enumerated services and processes are clearly desirable, it is not as clear that the responsibility for them is appropriately or reasonably placed on organizations whose business is primarily insurance coverage. Although it may be reasonable to expect coordinated care plans to undertake these coordination, continuity, and integration requirements, it is less clear that MA PFFS plans, MSAs, and (to a lesser extent) local PPO plans and MA regional plans (which will be offered as PPOs) should also be expected to. One might argue that continuity of care rules cannot apply in the same manner to MA plans in which the enrollee is free to choose his or her own providers without restraint, such as MSAs and PFFS plans. We stated that we were considering eliminating most of the requirements in § 422.112(b) for MSAs and PFFS plans. We also stated that we were considering eliminating or modifying many of the requirements in § 422.112(b) for local PPOs and regional MA plans. Finally, we stated that we were considering the continued appropriateness of these continuity of care standards for all other coordinated care plans. We specifically welcomed input on the extent to which requirements similar to those in § 422.112(b)(1) through (b)(6) are established for commercial health insurers offering HMOs, PPOs or indemnity plans.

Based on comments we received, we will continue to apply existing continuity of care requirements in § 422.112(b)(1) through (b)(6), but we will limit their scope of applicability to coordinated care plans and then only to the services provided and coordinated by contracted, network providers.

Comment: Many commenters provided input on this issue. A large number of commenters stated that continuity of care and integration of services is a key aspect of managed care. To the extent the original FFS Medicare program has been perceived to be deficient in this aspect of health care delivery, many commenters believe that CMS should ensure that a similar ''failure'' in managed care is not allowed. A number of commenters supported the removal of continuity of care requirements related to MA MSA and PFFS plans in recognition of the fact that these types of MA plans are primarily in the business of paying claims and not in the business of coordinating health care through contracted networks of health care providers. Other commenters stated that it was especially for MA plans that did not have contracted provider networks, such as PFFS plans or MSA plans, that continuity of care requirements were most needed.

Some commenters agreed with CMS proposal to eliminate and/or reduce continuity of care requirements for open network MA plans, such as PFFS plans and PPO plans. Other commenters suggested removing all continuity of care requirements for all MA plans, saying that such requirements were duplicative of QI program activities required under section 1852(e) of the Act.

Response: Based on the comments, and because PPOs operate as both coordinated care plans and ''open network'' plans at the same time, we will modify this portion of the regulation. We will specify in § 422.112(b) that the enumerated coordination of care requirements in § 422.112(b)(1) through (6) are applicable only to coordinated care plans. We will also limit applicability of coordination of care requirements to only contracting, in-network providers, thus limiting applicability for MA PPOs to only those services provided by contracted providers. We believe such an approach strikes the appropriate balance between the need for coordination and continuity of care and the burden associated with seeking to undertake such activities in the absence of contractual relationships with providers.

Finally, we do not agree that continuity of care requirements are duplicative of QI program activities required under section 1852(e) of the Act. QI activities will generally and primarily be focused on individuals with multiple or severe chronic conditions. Access to an initial health assessment, on the other hand, as provided in § 422.112(b)(4)(i), should include all enrollees of an MA coordinated care plan, and not only those with multiple or severe chronic conditions.

Comment: A few commenters stated that CMS appeared to be deleting a paragraph (i) from paragraph (b)(4) in the regulations text at § 422.112, but had no corresponding discussion in the preamble of the proposed rule.

Response: We thank the commenters for identifying this oversight and have corrected the regulations text related to § 422.112(b)(4) to show that none of the subparagraphs is to be deleted and that renumbering is unnecessary.

Access ''Exception'' for MA Regional Plans

The MMA created a special access rule for MA regional plans in the form of an ''essential hospital'' payment. Section 1858(h) of the Act and implementing regulations related to ''essential hospitals'' are discussed in greater detail later in this section of the preamble.

We noted that in attempting to create region-wide networks, MA regional plans will be forced to bargain with hospitals that may be the only hospital (or the only hospital with a particular service or services) in a broad area. We believed that such a hospital would have a ''monopoly power'' in negotiating with plans that are, in effect, forced to contract with it in order to secure an adequate network of contracted providers with which to serve anticipated Medicare enrollees. The MMA attempted to partly address this situation through a provision that would make limited funds available to supplement payments to such ''essential hospitals.'' We proposed an additional special access requirement that also would only apply to MA regional plans at § 422.112(a)(1)(ii).

In § 422.112(a)(1)(ii), we proposed an ''exception'' to the normal access requirements that would otherwise apply to MA regional plans by adding language that provided for a relaxation of comprehensive network adequacy requirements, but only to the extent that beneficiaries were not put ''at risk'' for high cost sharing related to services received from non network providers. We believed that flexibility did not need to apply on a plan-wide basis, but rather could be applied in a county or a portion of a region where, for example, the MA regional plan was unable to secure contracts with an adequate number of a specific type of provider or providers to satisfy our comprehensive network adequacy requirements that

would otherwise apply to coordinated care plan models.

We considered two forms of beneficiary cost sharing. One was the cost sharing related to a specific item or service—for instance, a hospital coinsurance charge. Another was the ''catastrophic limits'' that MA regional plans must apply to original Medicare FFS benefits. MA regional plans are required to provide reimbursement for all covered benefits regardless of whether those benefits are received from network providers (see section 1859(b)(4)(B) of the Act and the new § 422.101(e)(1)). MA regional plans are also required to apply a catastrophic out-of-pocket limit on beneficiary cost sharing for covered in-network services and another on all covered services (in and out-of-network). See section 1858(b)(2)(B) of the Act and the new § 422.101(d)(2) and (d)(3).

We proposed to permit MA regional plans with lower out-of-network cost sharing to have less robust networks of contracted providers and to permit MA regional plans with more robust networks of contracted providers to impose higher cost sharing charges for out-of-network services. This was because to the extent the plans' networks were robust, we would not expect beneficiary access to be unduly limited by higher cost-sharing requirements when care was sought from non-network providers. However, for plans with less robust networks, we proposed to limit the plans' ability to impose higher cost-sharing requirements for out-of-network care. We believed that higher cost-sharing requirements imposed by plans with limited provider networks could unduly limit access and that more equitable cost-sharing requirements would serve as a safety valve to ensure that beneficiary access is not compromised. We discussed various methods for testing the robustness of MA regional plan provider networks. Along similar lines, we would require MA regional plans with a less robust network of contracted providers to have ''catastrophic limits'' on out-of-pocket expenditures for in-network and for all services that are closer in value. For plans with more robust contracted networks, we would allow the in-network and total ''catastrophic limits'' to differ to a greater degree.

Based on the comments we received and which we respond to (below), we will not be prescribing specific levels of cost sharing based on robustness of contracted provider networks. Rather, we will require MA organizations sponsoring MA regional plans to ensure enrollees have access to in-network levels of cost sharing for covered services. We will require MA organizations sponsoring MA regional plans to reduce cost sharing to in-network levels for the receipt of out-of-network services in cases in which covered services cannot be readily obtained from contracted, network providers.

In this part of the preamble of the proposed rule we also discussed the OPM requirement imposed on the FEHB Blue Cross and Blue Shield Basic Option plan, which addresses similar circumstances and situations encountered by Federal employees and annuitants when seeking health care. We stated that the ''exception'' process related to access to care requirements for MA regional plans might require the MA regional plan enrollee to contact the sponsoring MA organization when seeking a specific service that is not otherwise available from a contracted provider. We are adopting that proposal. We will require MA organizations sponsoring MA regional plans to designate a non-contracted provider from whom (or from which) the enrollee can obtain covered services at network cost-sharing levels, to the extent that such services are not available and accessible from a contracted, network provider. Alternatively, the MA organization can allow the enrollee to seek the service from any qualified provider and guarantee that in-network cost sharing limits will apply. We have established a new beneficiary notification requirement related to enrollees of MA regional plans in § 422.111(b)(3)(ii). We add this requirement to ensure that the access ''exception'' in § 422.112(a)(1)(ii) does not disadvantage beneficiaries seeking in-network care.

Comment: Several commenters were received on this proposed provision. Many of the commenters suggested that the ''exception'' should also apply to all local MA coordinated care plans, or even all local MA plans, while others suggested limiting it to local and MA regional PPOs.

Response: Local MA plans of all types have discretion to limit their service areas based on their network of contracted providers. Unlike local MA plans, MA regional plans are required, as a condition of offering an MA regional plan, to include the entire geographic area of an MA region in the service area of the plan. In some ways, the ''exception'' we provide at § 422.112(a)(1)(ii) for MA regional plans is comparable to the ''partial county'' provision provided for local MA plans in the service area definition at § 422.2. Under § 422.2, we permit an MA organization to contract with CMS for a local MA plan where the organization has a contracted network in only a portion of a county and when such a ''partial county'' is necessary, nondiscriminatory, in the best interests of the beneficiaries and where other conditions are met. We will also permit MA organizations to contract with CMS for an MA regional plan where beneficiaries are not put ''at risk'' even though the MA organization does not have contracts with robust networks of providers throughout the MA region. For these reasons, it is both inappropriate and unnecessary to provide such an ''exception'' for local MA plans.

Comment: Other commenters were opposed to allowing an ''exception'' to the normal access to care requirements to any MA coordinated care plan, including MA regional plans. One commenter suggested limiting the ''exception'' to only an initial start-up period, the first contract year, for instance even for MA regional plans.

Response: As noted above, we believe the ''exception'' we proposed for MA regional plan access to care requirements is essential to foster the growth of the MA regional plan program, a goal consistent with the Congressional intent in creating the program. We are concerned that in the absence of this ''exception,'' the provisions we discuss below related to beneficiary access to ''essential hospitals'' would not be sufficient to allow MA regional plans to meet access to care requirements for coordinated care plans.

The ''exception'' we provide at § 422.112(a)(1)(ii) is necessary because ''essential hospitals'' will not be contracting with MA organizations for MA regional plan members, but will be a necessary part of the MA regional plan's network in order for the MA regional plan to meet the applicable provider access requirements under section 1852 of the Act. Section 422.112(a)(1)(ii) acknowledges that some providers, such as ''essential hospitals,'' will not have a contract, but will be considered part of the network because they will be providers at which beneficiaries can seek care at in-network cost sharing levels. We do not believe it is appropriate to limit the ''exception'' to an initial start-up period, particularly because the ''essential hospital'' provision is not so limited. On the other hand, we agree that it would be appropriate to annually evaluate the ''subsection d'' hospitals that have been designated as ''essential hospitals'' by MA regional plans to ensure that the

conditions that permitted such designation continue to exist.

Therefore, we have added a requirement at § 422.112(c)(7) under which we will evaluate the continued applicability of ''essential hospital'' status on an annual basis at the time of annual contract renewal. Please see below for a more extensive discussion of ''essential hospitals.''

Comment: A few commenters suggested that CMS subject MA organizations offering MA regional plans to review by external entities and the general public to ensure that MA regional plans meet community access standards.

Response: We do not believe a mandatory external review of network adequacy is appropriate because the delay and burden associated with such a process could negate the competitive and market forces that the Congress intended should apply in the regional MA program. Ultimately, such a result could have the very effect the commenters are seeking to avoid, an adverse impact on beneficiary access. Section 1852(e)(4) of the Act provides for a private accreditation organization's external review of MA organizations in specific areas, including access to services. Nothing in section 1852(e)(4) can be construed as imposing mandatory external review on an MA organization of the type the commenters propose. Otherwise, the time frame between an organization's submission of an application for an MA contract year and CMS' approval or denial of that application would be too short to permit sufficient time for a formal, public comment period.

Comment: Many commenters expressed concern that CMS seemed to be relaxing the community access standards with the ''exception'' process we provided for MA regional plans in § 422.112(a)(1)(ii). Some commenters stated that to the extent CMS will pay MA regional plans more through various mechanisms, such as the ''stabilization'' fund, risk corridors in 2006 and 2007, and the new MA payment formula, therefore CMS also has reason to hold them to the same access standards to which CMS holds local MA plans. Other commenters supported the ''exception'' process and suggested that it be extended to local MA PPOs.

Response: As we have previously said, we will not permit local MA coordinated care plans to take advantage of the ''exception'' process in § 422.112(a)(1)(ii). The exception process is necessary precisely because we will require MA regional plans to meet community access standards. We explained in the proposed rule that to the extent an MA regional plan is unable to secure contracts with specific providers in specific areas of an MA region, beneficiaries would nonetheless be protected from excessive out-of-network cost sharing. In other words, it is exactly because we will continue to enforce community access standards that we will require MA regional plans to reduce cost sharing to in-network levels where covered services cannot be readily obtained from contracted, network providers. We establish a new beneficiary notification requirement related to enrollees of MA regional plans in § 422.111(b)(3)(ii) to reinforce this concept.

Comment: Some commenters stated that CMS should require hospitals to treat MA regional plan enrollees when they are offered the Medicare FFS payment rate that is payable under section 1886 of the Act by an MA regional plan, as long as in-network cost sharing levels are applied to enrollees that seek care at such non-contracting hospitals. One commenter stated that sole community hospitals, or hospitals serving medically underserved areas or non-urban areas should be required to treat MA regional plan enrollees if they refused to contract for FFS rates. One commenter recommended that CMS reevaluate the non-discrimination obligation of hospitals under the Medicare program and suggested that CMS establish a policy that would promote access to services at hospitals participating in the Medicare program on the same basis for all Medicare beneficiaries, regardless of whether they are MA enrollees or receiving coverage under the Medicare FFS program. One commenter recommended that CMS develop further regulations that would require providers to treat MA patients in all cases, even for elective services.

Response: We do not necessarily agree that we should establish a policy that would require Medicare participating hospitals to treat MA enrollees or to contract with MA organizations under specific terms or conditions. Were we to establish a specific price relative to FFS inpatient hospital payment rates as a baseline that would compel a hospital to treat MA plan enrollees, for instance, we would also be administering inpatient hospital pricing. We do not believe that a requirement to treat for an administered price is consistent with the overall intent of the MMA to increase plan choices for Medicare beneficiaries through competitive market forces. However, we acknowledge that MA provider contracting, especially in areas where there are few available providers, is a concern. We will continue to evaluate our current authorities outside of the MMA as a means of ensuring reasonable access at reasonable prices to medical services for all Medicare enrollees, including those electing to receive their coverage through an MA plan.

Comment: Some commenters stated that the ''exception'' CMS proposed in § 422.112(a)(1)(ii) would tend to put providers at a disadvantage vis-à-vis MA regional plans. The commenters stated that MA regional plans would offer reimbursement rates below FFS rates and as such, unilaterally dictate the terms of the contract. The commenters stated that this would be unfair to physicians and other providers. The commenters also stated that this would create an unfair playing field, especially because MA regional plan enrollees in such an area would then be required to go out-of-network at higher cost sharing levels, to receive covered medically necessary care.

Response: We disagree. MA regional plans will be required to make all covered services available at in-network cost sharing levels, even if an MA regional plan fails to reach mutually agreeable contracting terms with a specific provider or group of providers. In other words, MA regional plan enrollees will have access to medically necessary covered health services at in-network cost sharing levels. The MA regional plan must meet the access requirements either through contracted providers or through the ''exception'' process discussed above. Because section 1852(a)(2) of the Act requires MA organizations that use a contracted network to pay non-contracting providers at the Medicare FFS rate, once the MA regional plan enrollee pays in-network cost sharing, the MA organization will be financially responsible for the rest.

Comment: One commenter stated that CMS should adopt URAC, NCQA or JACHO standards related to MA PPO network adequacy requirements and privacy of beneficiary information requirements. The commenter stated that for network adequacy requirements and privacy requirements, as for all other federal regulatory requirements, to the extent that any accreditation standard of any of the three accrediting bodies applies to the same activity, compliance should be deemed for the PPO to be in compliance with the federal requirement.

Response: We do not necessarily agree. Under section 1852(e)(4) of the Act, when a private accrediting organization applies and enforces certain enumerated requirements that meet or exceed CMS standards, CMS can deem that an MA plan has met such

requirements. These enumerated requirements include access requirements under section 1852(d) of the Act and confidentiality requirements under section 1852(h) of the Act. To the extent the one of the three named parties has applied to CMS and been approved in accordance with statutory and regulatory requirements to be a private accrediting organization for external review of PPO access and/or confidentiality requirements, then deeming would be permissible. Note, however, that this deeming mechanism applies only for the purposes of CMS' enforcement of this regulation and neither CMS' enforcement of the regulation nor accreditation by an accrediting body supersedes the jurisdiction of the HHS Office for Civil Rights to enforce the HIPAA privacy rule.

Comment: One commenter asked whether the access ''exception'' in § 422.112(a)(1)(ii) for MA regional plans would preempt State licensing laws related to HMO access requirements.

Response: MA regional plans are offered as PPOs and not HMOs. We responded to a similar inquiry in the June 2000 M+C final rule with comment (65 FR 40257). An entity does not have to have a commercial license of the same type of MA plan it seeks to offer under the MA program. Rather, the entity must demonstrate that it is authorized by the State to assume the risk involved in offering the type of plan it wishes to offer. Thus, an entity that is licensed by the State to assume risk commercially as an HMO would need to demonstrate that it is authorized by the State to offer a PPO product. The access standards that would apply to such an MA product would be the MA PPO access standards.

Comment: Two commenters stated that CMS should rely on MA regional plans to demonstrate access to covered services throughout their service areas at in-network cost sharing amounts and that should CMS continue to review cost sharing levels to ensure that they are not discriminatory.

Response: We agree with this comment and will continue to review cost sharing levels as a means of ensuring beneficiary access to care and that cost sharing is not discriminatory. When we evaluate access to care for an MA regional plan that relies, in part, on the ''exception'' in § 422.112(a)(1)(ii), we will evaluate the means by which the MA regional plan proposes to ensure that access requirements are met. Such means might include the designation of ''essential hospitals'' in accordance with § 422.112(c), the designation of other noncontracting providers from which an MA plan enrollee can obtain covered plan services at in-network cost sharing levels (including the catastrophic limit described in § 422.101(d)(2)) in a timely manner, and the manner in which MA regional plan enrollees will be notified as to how they can secure in-network cost sharing when covered services are not readily available from contracted providers, in accordance with § 422.111(b)(3)(ii).

Unlike local coordinated care plans, such as MA local HMOs and MA local PPOs, where we have historically required comprehensive contracted networks of providers as a condition for meeting our access requirements, we will allow MA regional plans to contract with CMS with less robust networks of contracted providers. As long as an entity proposing to offer an MA regional plan pays noncontracted providers at the Medicare FFS rate, and as long as they can guarantee access through such payment to non-contracting providers, and as long as they limit enrollee cost sharing liability to in-network levels, then we will contract with such an entity for an MA regional plan as long as other non-access requirements are met.

Comment: One commenter stated that the ''exception'' at § 422.112(a)(1)(ii) is not in the best interest of beneficiaries and that neither the preamble nor the regulation text in the proposed rule said how promptly an MA regional plan would be required to respond to a request for access to non-network sources of care, or the basis upon which such a request could be denied, or the penalty to the MA regional plan for not acting in a timely manner on such a request, or finally, what recourse the member would have if a denial or non-response from the MA regional plan occurred.

Response: An MA regional plan would be required to provide assurances of reasonable response times, if it proposed to use the ''exception'' in § 422.112(a)(1)(ii) in such a manner. Reasonable response times proposed by the MA regional plan would need to be consistent with community patterns of care. Where a routine or follow-up specialist visit might ordinarily be available within 30 days, an MA regional plan would be expected to respond in such a manner that the MA regional plan enrollee could secure covered specialist services within a similar time frame. Similarly, as part of the MA plan's disclosure to both CMS and an MA regional plan enrollee, we would require a full explanation of the denial process (where services are readily available from contracting providers, for instance) and the appeal process the enrollee should follow in cases of disagreement. The potential penalty to the MA regional plan for not acting in a timely manner on such a request is explained in our current regulation at § 422.750 and § 422.758 for a violation of § 422.752(a)(1) and § 422.510(a)(10), respectively.

Essential Hospitals

We proposed at § 422.112(c) that if an MA organization certifies that it was unable to reach an agreement with an ''essential hospital,'' under specific circumstances we are authorized to pay additional amounts to that hospital from the Federal Hospital Insurance Trust Fund. This additional payment to the ''essential hospital'' is in addition to and does not affect the normal monthly MA payment that we would make to the MA organization. The MA organization must provide assurances that it will make payment to the hospital for inpatient hospital services in an amount not less than the amount that would be payable under section 1886 of the Act and the ''essential hospital'' must demonstrate to our satisfaction that the amounts normally payable under section 1886 of the Act are less than the hospital's costs for providing services to MA regional plan enrollees.

Comment: A number of general comments were received on potential contracting difficulties between rural providers and health plans. On the one hand, several commenters were concerned that MA organizations offering MA regional plans would not make a ''good faith'' effort to contract with hospitals, especially hospitals located in rural areas. On the other hand, several commenters suggested that MA organizations offering MA regional plans in areas with limited competition could be ''held up'' for non-competitive or predatory payment rates as a condition of securing a contract with a specific provider. The commenters on both sides recommended various solutions, such as mandating the method by which MA organizations offering MA regional plans could show they have made a ''good faith'' effort to contract with providers.

Response: In response to comments that an MA regional plan should be required to show that it made a ''good faith'' effort to contract with an ''essential hospital,'' we added a requirement at § 422.112(c)(3) that the MA regional plan will need to establish its ''good faith'' effort by showing that the designated hospital refused to contract after it was offered a payment rate no less than the amount the

hospital would receive under section 1886(d) of the Act.

We agree that in certain rural areas, difficulties may arise in obtaining contracts that will satisfy the providers or the health plans, or both. However, we do not have the statutory authority to mandate contracts between MA plans or providers, or to intervene in contract negotiations. Section 1854(a)(6)(B)(iii) of the Act prohibits us from intruding in the contractual relationships between MA organizations and health care providers. This prohibition is intended to ensure that free market conditions continue to promote competition and efficiency in the MA program. We believe that it is clear that the Congress provided incentives for MA regional plans in the form of additional payments through the stabilization fund and risk sharing in 2006 and 2007, neither of which is provided for local MA plans.

Additionally, the Congress also provided for payments for noncontracting acute care hospitals that provide inpatient hospital services to MA regional plan enrollees through the ''essential hospitals'' authority. As stated previously, we believe competition will be the best method of ensuring network adequacy because enrollees will favor and enroll in plans with more extensive networks and tend to avoid those without. Competition will also allow the more efficient health care providers to offer discounted rates to MA organizations, which will, in turn be able to pass these savings on to enrollees in the form of additional health care items and services or reduced premiums.

Finally, we believe enrollees will be attracted to MA organizations that contract with efficient providers, because costs will be lower. Clearly, the competitive forces are more complex than we can address in this forum. We have been careful not to disturb the new competitive balance created by the MMA related to MA regional plans.

Our access standards are found at § 422.112, § 422.114, and in other sections of subpart C of the MA regulation. These standards must be met before an MA organization will be allowed to offer an MA plan in an area. Continuing compliance with these requirements is an essential condition of maintaining an MA contract. For instance, CMS has the authority, provided at § 422.502(a)(3)(ii) and § 422.512(a), to deny an application or to terminate a contract if an MA organization fails to establish or maintain adequate access to care for Medicare beneficiaries. In order to meet access standards, MA organizations offering coordinated care plans will generally need to secure contracts that they have negotiated with health care providers. This will require an effort by both parties to ensure a choice of health plans with strong provider networks that will be available to all beneficiaries, including those residing in rural areas.

Comment: One commenter stated that in the State in which it operates, the contracts it has with hospitals for all lines of business (Medicare, Medicaid, and commercial) cause it to pay more on the Medicare side, that cost-shifting occurs from its Medicare line of business to its commercial line of business. The commenter expressed concern that to the extent the ''essential hospital'' provision permits an MA regional plan to ''deem'' a hospital into the MA regional plan's network, that it provides an unfair competitive advantage to MA regional plans. The commenter also suggested permitting hospitals to select a single Medicare contractor (section 1876 cost, MA local or regional plan) with which to contract, and through such a contract ''immunize'' itself from all other MA regional plans' attempts to designate it as an ''essential hospital.''

Response: We do not believe it would be appropriate or reasonable to so allow a hospital to ''immunize'' itself from designation as an ''essential hospital'' by any MA regional plan. To the extent we accepted or adopted such an interpretation, we would also be nullifying the very intent of the ''essential hospital'' statutory provision. The intent of this provision is, simply put, to ensure access to hospital care for regional MA plan enrollees. The opening clause of section 1858(h)(1) of the Act is instructive in this regard: ''For purposes of enabling MA organizations that offer MA regional plans to meet applicable provider access requirements under section 1852 with respect to such plans.'' Additionally, as we provide for in regulation at § 422.112(c), before a hospital can be designated as an ''essential hospital'' by an MA regional plan, there must be a showing by convincing evidence that such a hospital is uniquely able satisfy the access requirements for the MA regional plan. If we were to limit designation of a specific hospital as an ''essential hospital'' to the first PPO in an MA region, we would also likely limit MA regional plan competition in all MA regions with rural areas to a single MA regional plan per region. Such a result clearly was not the intent of the statute.

In addition, the ''essential hospital'' provision partly addresses hospital financing issues, to the extent that we will pay additional costs to ''essential hospitals,'' up to the amount provided in statute at section 1858(h)(3) of the Act. Thus, the MA organization would not bear these additional costs for MA regional plan enrollees.

Comment: One commenter asked for clarification on how payment will work under the ''essential hospital'' provision. While the statute is clear, the commenter stated, that the additional payment is limited to inpatient services, it is unclear to the commenter whether add-ons such as medical education or disproportionate share payments will also be made to ''essential hospitals.'' The commenter recommended that CMS encourage or even require plans to provide additional reimbursement to include these amounts, which are available under inpatient PPS, to qualifying hospitals because they would be available if the beneficiary were enrolled in FFS Medicare.

Response: IME and GME payments will continue to be made by the Medicare fiscal intermediaries (FIs) to all appropriate hospitals for all Medicare beneficiaries (including MA plan enrollees). Disproportionate Share Hospital (DSH) payments are part of the normal FFS reimbursement amount and will be the responsibility of the MA regional plan, to the extent it is making a payment under § 422.100(d)(2), because, by definition, ''essential hospitals'' are defined as noncontracting hospitals per section 1858(h)(1) of the Act. In our regulation at § 422.112(c), we clarify that ''essential hospitals'' are always noncontracting with the specific MA regional plan involved.

Comment: Some commenters suggested that to the extent an MA regional plan offers to pay a hospital no less than the amount that would be payable to the hospital under section 1886 of the Act, that CMS consider this to be evidence that the MA regional plan has made a ''good faith'' effort to contract with the hospital.

Response: We agree with the commenters and have established the FFS payment level as the baseline for MA regional MA plans in establishing that they have made a ''good faith'' effort to contract with an ''essential hospital'' at § 422.112(c)(3).

Comment: Many commenters recommended that CMS specify in regulation exactly how the ''essential hospital'' provision will work and whether or not (and how) it would apply to critical access hospitals (CAHs). Other commenters cautioned CMS not to disrupt the competitive balance between MA organizations and hospitals related to MA plan contracting. Many commenters also recommended that CMS clearly explain

that CAHs are not ''essential hospitals'' as defined in the MMA. Other commenters stated that CAHs are indeed essential providers and have been designated as such under the FFS Medicare program. Some commenters suggested requiring MA regional plans to pay CAHs the ''interim'' Medicare rate in effect at the time the service was furnished.

In addition, one commenter stated that such an ''interim'' payment rate would put parties at risk that such a payment would be more (or less) than actual costs. The commenter also suggested that CMS devise a means of ensuring that MA regional plans are properly advised on the ''interim'' payment rate, should CMS accept the commenter's proposal. Still other commenters stated that CMS should not permit MA organizations to bargain in ''bad faith'' with hospitals. However, other commenters stated that CMS should not permit hospitals to bargain in ''bad faith'' with MA organizations. In general, all expressed concern and cautioned CMS not to upset the delicate balance of competition and pointed to the scarce resources and fragile financial condition of health care delivery in rural areas.

Generally, CMS was asked not to undermine the already precarious condition of rural providers, including rural health clinics, CAHs and others, while at the same time we were encouraged to increase the availability of MA plans in rural areas. One commenter recommended that CMS put in a ''hold harmless'' or ''cost-reimbursement'' requirement for insurers that contract with critical access hospitals. The commenter was concerned that as more Medicare beneficiaries opt for participation in private insurance plans, unless CAHs receive adequate funding for the services they provide, their continued existence (and consequently continued access to medical care for the beneficiaries they serve) will be greatly jeopardized. Another commenter suggested that CMS require MA plans to provide reimbursement to CAHs using a cost-based methodology similar to that required under FFS Medicare.

Another commenter stated that as more Medicare beneficiaries enroll in MA plans that do not contract with CAHs, the marginal costs (per Medicare beneficiary) at CAHs will rise and so, consequently, will Medicare payments per FFS beneficiary to CAHs. A few commenters suggested extending the ''essential hospital'' payment to local MA plans. Other commenters called on CMS to require MA plans to pay claims from noncontracting providers in a ''timely'' manner and under the same rules that apply to original FFS claims processors, the Medicare carriers and intermediaries.

In addition, several commenters expressed confusion with the following sentence from the subpart C preamble to the August 3, 2004 proposed rule: ''In a specific case, the actual payment to an 'essential hospital' from the Federal Hospital Insurance Trust Fund would be the sum of the difference between the amount that would have been paid to the hospital under section 1886 of the Act and the amount of payment that would'' have been paid for those services had the ''essential hospital'' been a critical access hospital.''

Response: We will address the last comment first. We need to clarify that the quoted sentence from the subpart C preamble of the August 3, 2004 proposed rule simply echoes the statutory language at section 1858(h)(2)(A) of the Act. The intent of the statutory ''essential hospital'' provision and the implementing regulation at § 422.112(c) is to provide an additional payment to the ''essential hospital'' of up to 101 percent of its actual costs for providing inpatient services to a specific MA regional plan enrollee. In other words, there was never an intent to designate or allow a CAH to become an ''essential hospital'' for purposes of the MA regional plan program. The definition of ''essential hospital'' in the statute prevents such an outcome. Section 1858(h)(4) of the Act is clear in defining an ''essential hospital'' as a ''subsection (d) hospital,'' as that term is defined at section 1886(d)(1)(B) of the Act. CAHs are not included in this definition and therefore can never be ''essential hospitals'' for purposes of an MA regional plan offered by an MA organization.

In § 422.112(c)(1), we are clear in limiting the applicability of the ''essential hospital'' provision in a similar manner to only hospitals defined in section 1886(d) of the Act, and thus excluding CAHs. We have addressed concerns related to maintaining a ''competitive balance'' previously in our responses in this section of the preamble. We cannot intrude in the contracting relationships between MA organizations and providers because the statute prohibits us from doing so at section 1854(a)(6)(B)(iii) of the Act. Additionally, to the extent the statute provides the additional ''essential hospital'' payment only for inpatient hospital services provided by 1886(d) hospitals to MA regional plan enrollees, we cannot extend its applicability to local MA plans of any type.

Comment: One commenter suggested that CMS maintain a comprehensive and accessible database of Medicare FFS reimbursement rates for all providers and allow MA plans access to the database so they would be better equipped to make the correct and full payment to out-of-network providers. The commenter also stated that there should be penalties or sanctions for plans that habitually under-pay out-of-network noncontracting providers. The commenter also suggested that CMS require MA organizations to follow FFS timely payment rules, including accrual of interest when claims are not paid in a timely manner. Some commenters stated that the additional difficulties inherent in paying CAHs timely and correctly, explaining that CAHs are paid on a ''cost plus'' basis.

Response: We provide public access to the FFS fee schedules and reimbursement rates. We also assists MA organizations in pricing claims for out-of-network providers by making ''Grouper/Pricer'' software and other Medicare claims'' pricing tools available to them. However, with payment rates and computations varying by provider type, locality, provider ID, and service, and with the potential that an MA plan enrollee might access covered emergency services in any part of the United States, the task of correctly applying fee schedules that are generally updated on a quarterly basis can be daunting. When one considers the low volume of such claims that an MA organization would expect to receive and the administrative effort involved in correctly pricing them, one begins to understand that simply making such data and systems available to MA organizations does not ensure that correct payment calculations will always occur. We already have the authority to apply penalties and sanctions to MA plans that habitually fail to pay out-of-network noncontracting providers in a timely manner (see, for instance, § 422.520). MA organizations are required to follow the same timely payment requirements related to con-contracting provider claims, including interest penalties, that apply to FFS carriers and intermediaries.

Although MA organizations are required to pay noncontracting providers the amount that would otherwise be payable under original Medicare (§ 422.100(b)(2), and although Medicare providers are required to accept from noncontracting MA organizations the amount original Medicare would have made (§ 422.214), the amount original Medicare pays to CAHs is paid on a periodic interim

basis, is cost-based, and is subject to cost settlement. Additionally, section 405(c) of the MMA provides for development of alternative timing methods for the periodic interim payments already made to CAHs for inpatient services. This provision will further complicate the computation of amounts due CAHs under Medicare and will represent an additional administrative burden on MA organizations offering MA regional plans that will need to pay noncontracting CAHs based on a number of unique and changing factors. Similarly, to the extent CAHs are located in areas served by MA regional plans, they would potentially suffer a disruption in the normal cash-flow provided for them through periodic interim payments in the Act, even were MA regional plans able to provide correct reimbursement amounts in a timely manner. Although timely reimbursement for claims received from noncontracting providers by MA organizations is already required (see § 422.520(a), the timely claims-payment standard (claims must be paid within 30 or 60 days, depending on whether they are clean claims), is not a substitute for the guaranteed cash-flow related to periodic interim payments made by the Medicare FFS intermediary to CAHs.

Additionally, to the extent CAHs settle costs with CMS related to services they provide to Medicare beneficiaries, MA organization computation of payments due CAHs is further complicated, because of the potential difference between the Medicare interim payment and the final settlement.

In light of the special status provided to CAHs in section 1820 of the Act and implementing regulations, and in recognition of the unique status of CAHs related to access to care for FFS beneficiaries, we also note a special concern for them related to the MA program and specifically to MA regional plans. While we are constrained by the non-interference clause in section 1854(a)(6)(B)(iii) of the Act from requiring MA organizations to contract with CAHs, or from requiring contracts voluntarily entered into with CAHs to specify the level or manner of reimbursement, we will increase our level of monitoring of CAHs. For instance, we might review MA regional plan payment to non-contracting CAHs during our routine biennial monitoring visits. We will use our authority in section 1857(f)(2) of the Act when needed to ensure MA organization compliance with existing non-contractor timely payment requirements. We do not interpret the statute to permit CMS enforcement of contracts voluntarily entered in to by MA organizations and health care providers. Although our regulations require that all MA organization contracts with providers and suppliers contain a prompt payment provision (see § 422.520(b)), details of such prompt payment provisions and enforcement thereof would be as specified in the contract.

Comment: One commenter requested clarification regarding the ''essential hospital'' payment from the HI Trust Fund. The ''essential hospital'' must demonstrate that the amount of the MA plan payment is less than the cost of providing services to MA regional plan enrollees. The commenter asked whether this additional payment is equivalent to the full PPS rate, or to cost (which may be greater than the PPS rate), or cost plus one percent (because of the reference to CAHs at section 1858(h)(2)(A)) of the Act. The commenter also recommended that CMS provide guidance on how the hospital will demonstrate it is eligible for an ''essential hospital'' payment. The commenter is concerned that the procedures that we establish not be too cumbersome so that the additional reimbursement is not sufficient to compensate for the reporting effort.

Response: The ''essential hospital'' will need to establish that its actual costs for providing inpatient care to a specific MA regional plan enrollee actually exceeded the amount that is normally paid under FFS Medicare. The amount normally paid under FFS Medicare is the PPS payment normally made to the ''subsection d'' hospital under Part A of the Act for similar inpatient hospital services provided to an original FFS Medicare beneficiary. As we have already discussed in this part of the preamble related to § 422.100, the normal PPS payment (less the amounts paid by the fiscal intermediary under sections 1886(d)(11) and 1886(h)(3)(D) of the Act) will be the responsibility of the MA organization sponsoring the MA regional plan in which the beneficiary is enrolled. Thus, after the normal FFS amount has been paid to the ''essential hospital,'' the ''essential hospital'' can seek additional funding from CMS for up to 101 percent of the inpatient costs it actually incurred in treating a specific MA regional plan enrollee. The availability of funds to make such an additional payment to ''essential hospitals'' is limited by section 1858(h)(3) of the Act. We have clarified in the regulatory text in § 422.112(c)(6) that we will pay from funds appropriated in section 1858(h)(3) of the Act until such funds are exhausted. In other words, we will pay based on the order in which claims from ''essential hospitals'' are received. Finally, we have prescribed in regulation the method through which an ''essential hospital'' will establish that its costs for treating a specific MA regional plan enrollee exceeded the normal PPS payment amount. We will use the principles of reasonable cost reimbursement in part 412 of this chapter to determine whether costs in a specific case exceed the normal PPS payment amount in an individual case. To the extent an ''essential hospital'' can show, using methods of reasonable cost reimbursement, that the amount it reasonably expended in its treatment of an MA regional plan enrollee exceeded the normal PPS reimbursement amount for inpatient services, then CMS will make an additional payment to the ''essential hospital,'' limited by the statutorily appropriated amount in section 1858(h)(3). The statute initially authorizes $25,000,000 in 2006 and increases the annual amount available for ''essential hospital'' payments in subsequent years by the market basket percentage increase as defined in section 1886(b)(3)(B)(iii) of the Act.

Comment: One commenter recommended that CMS eliminate ambiguity and to clearly define which types of hospitals are eligible for ''essential hospital'' designation.

Response: Our regulation indicates that any ''subsection (d)'' hospital can qualify as an ''essential hospital.'' The regulation mirrors the statute in this respect. Note that ''subsection (d)'' hospitals are defined in statute at section 1886(d)(1)(B) of the Act and refer to hospitals paid under a ''prospective'' (PPS) method. We have added language to § 422.112(c)(1) to clarify this issue. Also note that we have further defined ''essential hospital'' in regulation text at § 422.112(a)(4) as one where there is no competing Medicare participating hospital in the area to which MA regional plan enrollees could reasonably be referred for inpatient hospital care. We believe MA organizations are in the best position to determine what is ''reasonable'' in this context, based on service usage and community patterns of care. However, we will evaluate such claims based on standards that will include: an evaluation of the ownership and control of other hospitals in the area; the normal patterns of community access; the physical proximity of other inpatient facilities; the referral patterns to inpatient facilities in the area; and other factors pertinent to the analysis.

Comment: A number of commenters recommended that CMS apply special rules to I/T/U hospitals so that all hospitals operated by I/T/U or the

Indian Health Service would be considered ''essential hospitals.''

Response: We cannot accommodate this request because there is no statutory basis for including all hospitals operated by Tribes or the Indian Health Service as ''essential hospitals.'' Section 1858(h) of the Act is explicit in defining ''essential hospitals'' as subsection (d) hospitals as defined in section 1886(d) of the Act. To the extent a Tribal or IHS hospital is designated by an MA regional plan under section 1858(h)(1) of the Act and to the extent all other conditions in section 1858(h) of the Act are present, then such a hospital can be an ''essential hospital.''

Comment: Some commenters recommended that CMS establish rules for ''essential hospitals'' that would require them to participate in the utilization management, discharge planning or quality improvement programs of the MA plans of the enrollees they treat.

Response: We will not separately establish such requirements related to ''essential hospitals.'' As ''subsection d'' hospitals, ''essential hospitals'' are already required to meet quality assurance, discharge planning and utilization management standards applicable to Medicare participating hospitals.

Comment: One commenter asked who would be responsible for the ''essential hospital'' payment, once the annual allocation specified in section 1858(h)(3) of the Act has been exhausted.

Response: In response to this comment, we have clarified this section of the regulation to say that once ''essential hospital'' payments exceed the limit prescribed in statute in a calendar year, no additional ''essential hospital'' payment will be due from any party. The statute is clear in allocating up to $25,000,000 for calendar year 2006 and a similar amount, adjusted for inflation, in subsequent years. We will make appropriate payments from the Part A Trust Fund on a ''first come-first served'' basis. We have specified these requirements in regulation at § 422.112(c)(6). Once the amount authorized in statute has been exhausted in a calendar year, no additional ''essential hospital'' payment is due nor can one be made by us for inpatient hospital services received by an MA regional plan enrollee in that calendar year.

Comment: One commenter asked if the in-network cost sharing requirement would still apply to services received in an ''essential hospital,'' even after the ''essential hospital'' allocation has been exhausted.

Response: To the extent an ''essential hospital'' is needed to meet the access requirements in § 422.112, we have added a requirement at § 422.112(c)(7) that in-network cost sharing applies to covered inpatient services received by an MA regional plan enrollee in an ''essential hospital.'' This is consistent with the ''exception'' in § 422.112(a)(1)(ii) and the beneficiary notification requirement in § 422.111(b)(3)(ii). The requirement for an MA regional plan to provide, or reimburse for, medically necessary inpatient hospital care (and to limit member liability to in-network cost sharing levels when reimbursing an ''essential hospital'') is independent of the ''essential hospital'' payment provision. Section 422.112(c)(7), where cost sharing is limited to in-network amounts for covered inpatient care reimbursed to an ''essential hospital'' by an MA organization for an MA regional plan member, applies even when § 422.112(c)(6) does not. Even if no ''essential hospital'' payment is due per § 422.112(c)(6) because conditions in § 422.112(c)(5) are not met (rather than due to exhaustion of the ''essential hospital'' annual allocation), in-network cost sharing for covered inpatient services at an ''essential hospital'' is still required. In other words, once a hospital is designated as an ''essential hospital'' by the plan, in-network cost sharing applies regardless of whether an ''essential hospital'' payment is due or paid.

Comment: One commenter said that to the extent the ''exception'' in 422.112(a)(1)(ii) is used, that not only normal per service in-network cost sharing should apply to services so obtained, but also that the in-network catastrophic limit on Medicare A/B services in § 422.101(d)(2) should also apply.

Response: We agree and reference the in-network catastrophic cost sharing limit in § 422.101(d)(2) as an additional limit on MA regional plan enrollee cost sharing liability in § 422.112(c)(7) when covered inpatient care is received at an ''essential hospital.''

Comment: One commenter asked whether we would permit or require MA regional plans to list ''essential hospitals'' in their provider directories. The commenter said that allowing an MA regional plan to so list ''essential hospitals'' would be inappropriate because such marketing would provide the hospitals with an advantage that should only accrue to contracting providers. We received a number of comments from other parties that objected to the listing of ''essential hospitals'' in MA regional plan provider directories on the basis that such a listing would provide the MA regional plan with an advantage that should only accrue to MA regional plans that actually have the ''essential hospital'' under contract.

Response: While we generally concur with both commenters that neither party is entitled to an undue advantage, MA regional plans are required to provide enrolled members a provider directory on an annual basis in accordance with § 422.111(a)(3). Note that as part of that requirement a description of any out-of-network coverage is also required. So, while it would not be permitted to list ''essential hospitals'' in an MA regional plan's provider directory as if they were contracting providers, it is also true that a description of their status as ''essential hospitals'' would be required.

12. Special Rules For Ambulance Services, Emergency Services, and Urgently Needed Services, and Maintenance and Post-Stabilization Care Services (§ 422.113)

We proposed to modify § 422.113(b)(2)(v) to clarify that the $50 limit for ''emergency services'' applies only to the emergency department, and that while the limit on cost-sharing for ''post-stabilization'' care at § 422.113(c)(2)(iv) continues to apply, its application would always begin upon inpatient admission. Thus, emergency cost-sharing limits would shift from being tied to the type of service (emergency services) to being tied to the site of service (emergency department). We believe that making this clarification retained cost-sharing limits for both emergency services and post-stabilization care, while eliminating the unanticipated complexities and administrative burden previously associated with this section of the regulation.

Comment: A number of comments supported the clarification that the $50 limit on cost sharing for emergency services applied only to emergency department services. Commenters supported the notion that once an MA enrollee is admitted to a hospital, normal hospital cost-sharing levels apply, even if the inpatient admission originates from the emergency department. On the other hand, many commenters recommended that CMS reexamine the $50 limit itself. Some commenters recommended that CMS set the limit higher (at $75, $100 or higher) and other commenters recommended that CMS index the emergency department cost-sharing limit for inflation.

Response: We believe that the $50 limit on cost sharing for emergency

department services continues to provide the appropriate financial disincentive to MA plan enrollees not to frivolously use emergency rooms in non-emergency situations. For instance, there is no MA plan currently imposing cost sharing for in-network physician office visits that approach $50. Similarly, MA organizations are permitted to deny emergency department services as medically unnecessary, to the extent that the member can be shown to have acted in ''bad faith'' or not as a ''prudent layperson'' in presenting at an emergency room for non-emergency services.

Finally, we do not set forth in regulation the maximum amount an MA organization can impose in cost sharing for receipt of urgently needed services. Because we have restricted the applicability of the $50 limit on enrollee cost sharing to emergency department services, we believe we have appropriately balanced the financial interests of MA organizations and MA plan enrollees requiring emergency services.

13. Access to Services Under an MA Private Fee-For-Service Plan (§ 422.114)

Section 211(j) of the MMA allows MA PFFS plans to charge higher co-pays to members who receive services outside of a PFFS plan's contracted network. This provision does not apply to PFFS plans that meet access requirements solely through ''deemed'' networks as defined in § 422.114(a)(2)(i). We proposed to add a new paragraph (c) to account for section 211(j) of the MMA.

We received no comments on this section, so we finalize as proposed.

14. Return to Home Skilled Nursing Facility (§ 422.133)

We proposed to extend the provisions in § 422.133 (Return to home skilled nursing facility) to SNF services provided in cases in which an MA organization elects, as permitted under § 422.101(c), to provide Medicare covered SNF care in the absence of a prior qualifying hospital stay. In such an instance, we proposed to require that an individual who would be eligible under section 1852(l) of the Act for admission to a ''home SNF'' upon discharge from a hospital stay, would nonetheless retain his or her right to receive ''home SNF'' benefits in the absence of such a hospital stay.

We proposed to deem that a hospital discharge has always occurred before an admission for SNF services, and therefore provide all MA enrollees full rights to the ''home SNF'' benefit.

We received no comments on this section, so we finalize as proposed.

Subpart D—Quality Improvement Program

1. Overview

The MMA amended section 1852(e) of the Act in a number of significant ways that will affect how MA organizations pursue their quality improvement activities. Below we summarize the proposed provisions and respond to the public comments. (For a more in-depth discussion of the provisions, please refer to the preamble to the proposed rule.)

Quality Improvement Program (§ 422.152)

To reflect the Congressional intent to refocus the section on quality improvement, rather than quality assurance, we changed the heading of § 422.152 to ''Quality improvement program.'' Proposed § 422.152 specified that each plan (except MA PFFS and MSA plans) offered by an MA organization must have an ongoing quality improvement program and that a chronic care program must be a part of this program.

We believe that the broad requirements in proposed § 422.152(d) for QI projects did not present an undue burden for MA organizations, as these organizations have significant experience in carrying out such projects under the current § 422.152(d) requirements that we believe are more prescriptive than those we proposed in the August 2004 proposed rule.

Our previous quality improvement requirements for M+C coordinated care plans focused on attaining improvement in specific clinical topics and included specific performance measures for improvement. As a result of the MMA amendments, we proposed that MA organizations have the flexibility to shape their QI efforts to the needs of their enrolled population. In addition, we continue, based on our interpretation of section 1852(e)(3)(B)(i) of the Act, to require MA coordinated care plans to collect, analyze, and report their performance using measurements outlined by us or to participate in surveys administered by us (for example, HEDIS, HOS, and/or CAHPS).

Proposed § 422.152(b)(4) would require MA local PPO plans that are offered by an organization that is licensed or organized under State law as a HMO, to follow the same quality improvement requirements as other MA coordinated care plans.

A. General Comments

Comment: A number of commenters made a variety of general comments about the proposed rule. These comments include: (1) require that plans disseminate educational materials to beneficiaries; (2) require that all plans review all problems that come to their attention; (3) CMS should recommend that plans seek Quality Improvement Organization (QIO) technical assistance; (4) require plans to have physician advisory committees, and that these committees advise CMS on performance measures; and (5) CMS should begin to provide information on MA quality starting in 2006.

Response: MA plans are responsible for ensuring that beneficiaries are fully informed of the benefits covered under the contract as part of its marketing material, evidence of coverage, and summary of benefits. We do not have any requirements that plans conduct educational programs. While the dissemination of educational materials may be worthwhile in improving health outcomes, we do not believe it should be mandatory. Most plans already provide QI, for example, in marketing materials. Furthermore, we post HEDIS and CAHPS data on the *www.Medicare.gov* web site. To the extent an MA plan decides to furnish educational materials to its enrollees, the plan is responsible for the type of information it wishes to furnish, and it is in the best position to determine which information is most appropriate for the enrolled population.

We agree with the commenter that plans should review all problems that are brought to their attention. Depending on the nature, extent, and substance of the problems, an MA plan may implement immediate corrective action, or may need to implement more systemic changes to address the identified problem.

We agree with the commenters and encourage plans to seek technical assistance from QIOs. Plans should review the current scope of work to determine the areas for which the QIOs can provide assistance; a draft outline of the 8th scope of work is available on our web site. Plans that seek QIO assistance will receive it on both Part C and Part D services.

We disagree with the commenters that propose that we require physician advisory committees. We do not believe this is necessary because most plans already have Medical Director committees that advise plans on QI measures. Moreover, at the national level, we have a physician advisory

committee. These bodies should ensure an appropriate level of physician input.

We agree with the commenters with respect to our providing information on quality measures. HEDIS and CAHPS data are already on our website (*www.Medicare.gov*), and the data has been available for several years

Comment: Several commenters stated that CMS should include PFFS and MSAs in all of the QI requirements. However, there were also commenters that supported the exclusion of these plans.

Response: Because section 722(a) of the MMA specifically exempts these types of plans from the majority of QI requirements, we have excluded them from the same requirements in the regulations. These plans, however, must meet the following requirements: maintain health information systems; ensure information from providers is reliable and complete; make all collected information available to us' conduct quality reviews; and take corrective action for all problems that come to their attention.

Comment: Several commenters have recommended that we provide payment incentives to MA plans for providing better quality care, also known as pay for performance (P4P).

Response: We agree with the commenters concerning the merits of P4P. We are very interested in this approach and believe that we should pay not just for providing a service but for results. P4P should stimulate care that is efficient and effective for every patient while eliminating waste. We are currently working on four P4P demonstration projects. These are as follows:

The Premier Hospital Quality Incentive Demonstration

The Premier Hospital Quality Incentive Demonstration is a 3-year project that will recognize and provide financial rewards to hospitals that demonstrate high quality performance in a number of areas of acute care. The demonstration involves a CMS partnership with Premier Inc., a nationwide organization of not-for-profit hospitals, and will reward participating top performing hospitals by increasing their payment for Medicare patients. Through the Premier Hospital Quality Incentive Demonstration, we aim to see a significant improvement in the quality of inpatient care by awarding bonus payments to hospitals for high quality in several clinical areas, and by reporting extensive quality data on our web site. Participation in the demonstration is voluntary and open to hospitals in the Premier Perspective system as of March 31, 2003.

Section 646—Medicare Health Care Quality Demonstration Program.

The MMA mandates a 5-year demonstration program to examine factors that encourage the delivery of improved patient care quality, including financial incentives, appropriate use of best practice guidelines, examination of service variation and outcomes measurement, shared decision making between providers and patients, appropriate use of culturally and ethnically sensitive care, and related financial effects associated with these factors. In the demonstration, Medicare may provide benefits not otherwise covered, but may not deny services that are otherwise covered against the wishes of beneficiaries. The demonstration is required to be budget neutral.

Section 649—Medicare Care Management Performance Demonstration.

The MMA mandates a 3-year demonstration program where physicians will be paid to adopt and use health information technology and evidence-based outcome measures to promote continuity of care, stabilize medical conditions, prevent or minimize acute exacerbations of chronic conditions, and reduce adverse health outcomes. The statute limits the program to four sites meeting eligibility criteria. Payment can vary based on performance; however total payments must be budget neutral. QIOs could help enroll physicians, evaluate their performance, and provide technical assistance.

The Physician Group Practice (PGP) Demonstration.

The PGP Demonstration rewards physicians for improving the quality and efficiency of health care services delivered to Medicare FFS beneficiaries. Mandated by Section 412 of the Benefits Improvement and Protection Act of 2000, the PGP Demonstration seeks to encourage coordination of Part A and Part B services, reward physicians for improving health outcomes, and promote efficiency through investment in administrative structure and process. Under the 3-year demonstration, physician groups will be paid on a FFS basis and may earn a bonus from savings derived from improvements in patient management. Annual performance targets will be established for each participating physician group equal to the average Part A and Part B expenditures of beneficiaries assigned to the group during a base period, adjusted for health status and expenditure growth.

We are also paying close attention to P4P for managed care plans. We are aware that MEDPAC has developed proposals along these lines in its June 2004 report. Furthermore, many private sector organizations are sponsoring such projects. See, for example, a compendium developed by The Leapfrog Group (*www.leapfroggroup.org*). In addition, the Agency for Healthcare Research and Quality (AHRQ) has sponsored an evidence based report entitled ''Strategies to Support Quality-based Purchasing: A Review of the Evidence,'' published in fall 2004, which includes managed care plans. Finally, we have a contract with the Institute of Medicine to study P4P, which will also address managed care.

B. Measures

This portion of the discussion addresses measures for all MA plans. A specific discussion of measures for PPOs appears below.

Comment: Several commenters stated that CMS should include measure reporting requirements in regulations.

Response: Based on past experience, we disagree with the commenters recommending that we include specific measure reporting systems in the regulation. We believe it is a better approach to provide specific guidance through the Medicare managed care manual rather than including specific requirements in the regulation. In this way, we have the flexibility to implement appropriate changes in the measure systems and individual measures in a more timely manner. The industry and accreditation organizations, are constantly making changes to these reporting systems. Thus, having more flexibility to change measures as well as add and delete measurements systems allows us to be more responsive to the state of the art as to measurement systems.

Comment: A commenter stated that performance assessment data is outdated and that CMS should not use HOS to rank plans because there is no benchmark.

Response: We disagree with the commenter. HEDIS, CAHPS, and HOS are updated on a regular basis. We recognize that there are no benchmarks currently available and therefore use relative ranking in the performance assessment data system. Benchmarks also refer to standards or minimum performance levels.

Comment: A commenter stated that CMS should use a standardized core set

of performance measures, clinical and non-clinical that are applied to all MA plans. The commenter suggested that CMS not require MA plans to demonstrate that QI program size and scope are proportionate to plan size.

Response: In general, we agree with the commenter that a standardized set of measures should be used across all plan types because it allows the greatest comparison among plans. The one exception as discussed later, is that we have decided to allow some variation in the early stages of the PPO program as compared to the HMO program. As also noted, MMA specifies a different set of requirements for PFFS plans and MSAs.

Comment: One commenter stated that CMS should compare quality measures of MA plans to those for the FFS Medicare program.

Response: On the *www.Medicare.gov* website, we provide consumer assessment data from CAHPS on FFS Medicare and the MA plans, as well as a comparison of an Original Medicare rate (on State and national levels) compared to the MA health plan rates on the HEDIS measure—Access to Ambulatory Health Services.

Comment: A commenter suggested that CMS reduce the burden on plans by reducing the number of measures or by conducting HEDIS by telephone.

Response: We agree that it is important to minimize the MA plans' reporting burden and do so by using data submission tools, systems, and processes that are consistent with HEDIS reporting for the plan's commercial lines of business.

We believe that it is not appropriate, however, to collect HEDIS measures by phone because information collected by phone is less reliable.

C. Special Needs Plans (SNPs)

Comment: Many commenters suggested that CMS develop special measures for specialized MA plans for SNPs. Several commenters suggested that CMS use the ACOVE measures developed by Rand. They further suggested that quality oversight should take into account the populations being served by the SNP. In addition, they suggested that CMS should ensure that SNPs have comprehensive and coordinated care.

Response: We agree with the commenters and have already indicated to several demonstration plans that have institutionalized populations and are converting to SNPs that HEDIS and HOS will not be required. Instead we will work with them to identify measures that are similar to the national nursing home quality measures reported on the Nursing Home Compare website at *www.medicare.gov* and the CHSRA quality indicators, both of which are derived from the Minimum Data Set (MDS). SNPs for dual eligibles will be required to meet the requirements of other MA plans. We are also willing to explore special measures with other types of SNPs.

We are certainly open to considering the ACOVE measures and will explore their feasibility. As to other aspects of quality oversight, we will apply the same basic types of quality requirements for all MA plans but take into account beneficiary needs for SNPs. As to comprehensive and coordinated care, SNPs will need to meet chronic care improvement program (CCIP) requirements.

Comment: A commenter recommended that SNPs should not serve dialysis patients. The commenter stated that CMS cannot monitor the quality of care provided to dialysis patients in managed care plans because dialysis providers do not bill Medicare for services to MA beneficiaries, thus, the ESRD Clinical Performance Measures data, which are extracted from billing information, are not available.

Response: We appreciate the concerns expressed by the commenter and will definitely take them into consideration. We anticipate that will be able to collect the data. However, at this time, we have not determined with certainty that we can and share the commenter's concern that we not approve the plans unless we can collect the data. In Subpart A of this preamble, we indicate that we are not setting forth a detailed definition of severe and disabling chronic condition for purposes of the definition of special needs individuals, and we will review and evaluate SNP proposals on a case-by-case basis. This evaluation will take into consideration whether we can collect sufficient quality of care monitoring data.

D. Report to the Congress

Comment: Some commenters expressed concern that CMS could not add measures without issuing a Report to the Congress as required under Section 1852(e)(3)(A). They suggested that because of several of the unique populations that might be served in SNPs, that CMS extend the Report to the Congress, and that CMS form an expert panel, enhance clinical knowledge on high risk populations, disseminate best practices, enhance coordination care, and refine payment to support outcomes.

Response: As indicated in the proposed rule, we interpret that this requirement does not prevent us from making changes within each of the existing measurement systems, such as HEDIS. Further, although we need to submit a Report to the Congress to add new systems, we do not interpret this to mean that we need the Congressional approval before we proceed to implement new systems.

E. Types of performance measures

Comment: A commenter suggested that CMS develop clearly defined, nationally recognized quality measures based on objective criteria for all facets of the Medicare program to truly achieve the MMA's goal of offering Medicare beneficiaries a meaningful choice. It is feasible that the measures be based on pharmaceutical information, medical claims, and other routine administrative information already easily accessible across the Medicare program.

Response: We will be pursuing the development of the measures and will take into consideration the commenter's suggestion.

2. Chronic Care Improvement Program Requirements (§ 422.152(c))

At proposed § 422.152(c), we would require that MA plans develop criteria for a chronic care improvement program. The criteria must–

- Include methods for identifying MA enrollees with multiple or sufficiently severe chronic conditions who would benefit from participating in a chronic care improvement program; and
- Provide mechanisms for monitoring MA enrollees that are participating in the chronic care improvement program.

Comment: A commenter recommended that CMS use the standard definition of disease management adopted by the Disease Management Association of America (DMAA) for the CCIP. The commenter also recommended that the CCIP be population based and that CMS focus on congestive heart failure (CHF), diabetes, and chronic obstructive pulmonary disease (COPD). They further suggested that CCIPs be accredited, and be evaluated on clinical quality, beneficiary and provider satisfaction, and impact on cost. Other commenters recommended that CMS provide maximum flexibility for plans as to these requirements. A commenter suggested that plans can identify patients from claims, self-reports, by providers, socio-economic data primarily using existing measures, for example, HEDIS to monitor plus other evidence-based measures. A commenter also suggested plans should use clinical variables, for example, weight, use of ACE inhibitors, health and functional status, emergency room and hospital

use, satisfaction, total costs, as measures for CCIP.

Response: We certainly encourage plans to consider the definition provided by Disease Management Association of America (DMAA), as well as the other aspects of the programs developed by DMAA. However, we believe it is premature to provide more prescriptive requirements. We will look for information on the CCIP pilot under section 721 of the MMA as well as the early stages of the MA plans' implementation of this section 722 CCIP to shape guidance for this component of the program.

3. QI Projects (§ 422.152(d))

While we proposed to delete many of the prescriptive requirements for QI projects that appeared in § 422.152(d), we still retained the basic requirements of the projects including the collection, analysis, and reporting of data. We believed, though, that MA plans should have the ability to select topic areas and proposed deleting the requirements of including the entire relevant population and having to do both national and statewide projects.

In proposed § 422.152(d)(1), we would require that QI projects be initiatives that include the entire organization and focus on clinical and non clinical areas. The projects would need to follow the current quality improvement process. We retained the provisions that QI projects must measure performance, and the interventions must be system-wide and include the establishment or alteration of practice guidelines. In addition, we propose to require that the projects focus on improving performance for the Medicare population and involve systemic and periodic follow-up on the effect of the interventions. To ensure that the measures (or quality indicators) used in QI projects are reliable and relevant for improving the health care and services furnished to MA enrollees, we proposed in § 422.152(d)(2) to require that the quality indicators be objective, clearly and unambiguously defined, and based on current clinical knowledge or health services research. The measures must also be capable of measuring outcomes, such as changes in health status, functional status, and enrollee satisfaction, or valid proxies of those outcomes. Likewise, we proposed in § 422.152(d)(3)to require that the data used in an MA plan's QI projects be valid and reliable and based on systemic ongoing collection and analysis of information. We also proposed in § 422.152(d)(4) that the interventions achieve demonstrable improvement.

Finally, in § 422.152(d)(5), we proposed to retain the requirement that MA plans report the status and results of their projects when requested by us. We believe that this reporting and review burden would be much smaller than the process used in the M+C program. We intend to provide further guidance on the reporting requirements later.

Comment: A commenter stated that QI should involve more than measure, intervene, and remeasure. The commenter also stated that it should set performance expectations, collect and analyze data, identify undesirable events, develop interventions, collect data to monitor improvement, and require that all plans meet the same QI requirements.

Response: We agree that all HMOS and PPOs should have to meet the same basic requirements as to QI projects, and the regulation requires this. However, although we will encourage plans to adopt the commenter's other recommended steps, we do not believe that it is necessary to build them into mandatory requirements. The requirements that we have already specified should be sufficient, and to add additional requirements will create unnecessary burden.

A. National projects

Comment: A commenter requested that CMS provide guidance to plans on the meaning of 'encouraging' physicians to participate in quality improvement initiatives. The commenter also proposed that CMS provide plans with the flexibility to design and conduct QI projects based on topics relevant to the plan's population. However, the commenter stated that CMS should continue to provide suggestions and examples of topics for QI projects that are relevant to the Medicare population. The commenter also suggested that CMS should provide guidance regarding meaning of ''sustained improvement,'' and consider evaluating clinical and non-clinical performance improvement using HEDIS and CAHPS 3.0H results.

Response: As to encouraging physicians to participate in QI projects, we recommend plans to coordinate their efforts with their providers. Some possible options are that the plans will send letters to their providers encouraging participation or pay them a bonus. This will be up to the plans. As indicated, we will provide suggestions as to topics for plan consideration and guidance on these topics. We will give further consideration to the suggestion of using HEDIS and CAHPS for evaluating QI projects.

Comment: Some commenters recommended that CMS require plans to participate in national projects.

Response: The MMA specifically deleted the requirement for national projects. We interpret the Congress's deletion of this requirement as an indication of its intent that participation in national projects not be required. Therefore, we are not requiring the projects, and we believe the best alternative is to encourage plans to participate voluntarily in our proposed national projects.

B. Racial-ethnic QI projects

Comment: Some commenters opposed elimination of the racial-ethnic QI projects, while one commenter supported its removal.

Response: The MMA specifically eliminated this requirement. Again, we interpret the Congress's deletion of this requirement as indicating its intent that plans not be required to pursue these types of projects. However, we encourage plans to consider pursuing such projects voluntarily. We have a current racial-ethnic national project that started in 2003 and will not be completed until 2005. We will share results of this project when it is completed. Lovelace Clinic Foundation was selected by us to develop two cultural competency guides through an AHRQ Integrated Delivery System Network Funding task order. The first manual, ''Providing Oral Linguistic Services: A Guide for Managed Care Plans,'' provides a practical step-by-step process for the improvement of oral language services to patients with limited English proficiency (LEP). The second manual, ''Planning Culturally and Linguistically Appropriate Services: A Guide for Managed Care Plans,'' assists health plans in assessing the ethnically diverse populations they may serve, and assessing the cultural competency of the managed care plan. Lovelace recently completed a report ''Evaluation of Usefulness of CLAS Guides to M+CO Plans'' which is available from AHRQ.

C. Performance levels

Comment: A commenter suggested that CMS set guidelines on the minimum percent of enrollees that are identified and managed. Others opposed the removal of requirements as to minimum performance levels, sustained improvement, and clinical-nonclinical requirements and external review.

Response: We retain our view from the proposed rule that plans should select topics areas that best meet their needs rather than being required to select both clinical and nonclinical